

Calendar No. 479

105TH CONGRESS
2^D Session
S. 2330

A BILL

To improve the access and choice of patients to
quality, affordable health care.

JULY 20, 1998

Read the second time and placed on the calendar

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105TH CONGRESS
2D SESSION

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To improve the access and choice of patients to quality, affordable health care.

IN THE SENATE OF THE UNITED STATES

JULY 17, 1998

Mr. LOTT (for Mr. NICKLES) (for himself, Mr. FRIST, Ms. COLLINS, Mr. JEFFORDS, Mr. ROTH, Mr. SANTORUM, Mr. HAGEL, Mr. GRAMM, Mr. COATS, Mr. LOTT, Mr. MACK, Mr. CRAIG, Mr. COVERDELL, Mr. McCONNELL, Mr. ABRAHAM, Mr. ALLARD, Mr. ASHCROFT, Mr. BENNETT, Mr. BOND, Mr. BROWNBACK, Mr. BURNS, Mr. COCHRAN, Mr. DOMENICI, Mr. ENZI, Mr. FAIRCLOTH, Mr. GORTON, Mr. GRAMS, Mr. GRASSLEY, Mr. HATCH, Mr. HELMS, Mr. HUTCHINSON, Mrs. HUTCHISON, Mr. INHOFE, Mr. KEMPTHORNE, Mr. LUGAR, Mr. MCCAIN, Mr. MURKOWSKI, Mr. ROBERTS, Mr. SESSIONS, Mr. SHELBY, Mr. SMITH of New Hampshire, Mr. SMITH of Oregon, Ms. SNOWE, Mr. THOMAS, Mr. THOMPSON, Mr. THURMOND, and Mr. WARNER) introduced the following bill; which was read the first time

JULY 20, 1998

Read the second time and placed on the calendar

A BILL

To improve the access and choice of patients to quality, affordable health care.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Patients’ Bill of Rights Act”.

4 (b) TABLE OF CONTENTS.—The table of contents for
5 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—PATIENTS’ BILL OF RIGHTS

Subtitle A—Right to Advice and Care

Sec. 101. Patient right to medical advice and care.

“SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

“Sec. 721. Patient access to emergency medical care.

“Sec. 722. Offering of choice of coverage options.

“Sec. 723. Patient access to obstetric and gynecological care.

“Sec. 724. Patient access to pediatric care.

“Sec. 725. Continuity of care.

“Sec. 726. Protection of patient-provider communications.

“Sec. 727. Generally applicable provisions.

Sec. 102. Effective date and related rules.

Subtitle B—Right to Information About Plans and Providers

Sec. 111. Information about plans.

Sec. 112. Information about providers.

Subtitle C—Right to Hold Health Plans Accountable

Sec. 121. Amendment to Employee Retirement Income Security Act of 1974.

**TITLE II—INDIVIDUAL RIGHTS WITH RESPECT TO PERSONAL
MEDICAL INFORMATION**

Sec. 201. Short title.

Subtitle A—Access to Medical Records

Sec. 211. Inspection and copying of protected health information.

Sec. 212. Amendment of protected health information.

Sec. 213. Notice of confidentiality practices.

Subtitle B—Establishment of Safeguards

Sec. 221. Establishment of safeguards.

Subtitle C—Enforcement; Definitions

Sec. 231. Civil penalty.

Sec. 232. Definitions.

TITLE III—GENETIC INFORMATION AND SERVICES

- Sec. 301. Short title.
- Sec. 302. Amendments to Employee Retirement Income Security Act of 1974.
- Sec. 303. Amendments to the Public Health Service Act.
- Sec. 304. Amendments to the Internal Revenue Code of 1986.

TITLE IV—HEALTHCARE QUALITY RESEARCH

- Sec. 401. Short title.
- Sec. 402. Amendment to the Public Health Service Act.

“TITLE IX—AGENCY FOR HEALTHCARE QUALITY RESEARCH

“PART A—ESTABLISHMENT AND GENERAL DUTIES

- “Sec. 901. Mission and duties.
- “Sec. 902. General authorities.

“PART B—HEALTHCARE IMPROVEMENT RESEARCH

- “Sec. 911. Healthcare outcome improvement research.
- “Sec. 912. Private-public partnerships to improve organization and delivery.
- “Sec. 913. Information on quality and cost of care.
- “Sec. 914. Information systems for healthcare improvement.
- “Sec. 915. Research supporting primary care delivery and access in underserved areas.
- “Sec. 916. Clinical practice and technology innovation.
- “Sec. 917. Coordination of Federal Government quality improvement efforts.

“PART C—FOUNDATION FOR HEALTHCARE QUALITY RESEARCH

- “Sec. 921. Foundation for Healthcare Quality Research.

“PART D—GENERAL PROVISIONS

- “Sec. 931. Advisory Council for Healthcare Quality Research.
- “Sec. 932. Peer review with respect to grants and contracts.
- “Sec. 933. Certain provisions with respect to development, collection, and dissemination of data.
- “Sec. 934. Dissemination of information.
- “Sec. 935. Additional provisions with respect to grants and contracts.
- “Sec. 936. Certain administrative authorities.
- “Sec. 937. Funding.
- “Sec. 938. Definitions.
- Sec. 403. References.
- Sec. 404. Study.

TITLE V—WOMEN’S HEALTH RESEARCH AND PREVENTION

- Sec. 501. Short title.

Subtitle A—Provisions Relating to Women’s Health Research at the National Institutes of Health

- Sec. 511. Extension of program for research and authorization of national program of education regarding the drug DES.
- Sec. 512. Research on osteoporosis, Paget’s disease, and related bone disorders.
- Sec. 513. Research on cancer.

- Sec. 514. Research on heart attack, stroke, and other cardiovascular diseases in women.
- Sec. 515. Aging processes regarding women.
- Sec. 516. Office of Research on Women's Health.

Subtitle B—Provisions Relating to Women's Health at the Centers for Disease Control and Prevention

- Sec. 521. National Center for Health Statistics.
- Sec. 522. National program of cancer registries.
- Sec. 523. National breast and cervical cancer early detection program.
- Sec. 524. Centers for Research and Demonstration of Health Promotion.
- Sec. 525. Community programs on domestic violence.

Subtitle C—Women's Health and Cancer Rights

- Sec. 531. Short title.
- Sec. 532. Findings.
- Sec. 533. Amendments to the Employee Retirement Income Security Act of 1974.
- Sec. 534. Amendments to the Public Health Service Act relating to the group market.
- Sec. 535. Amendment to the Public Health Service Act relating to the individual market.
- Sec. 536. Amendments to the Internal Revenue Code of 1986.
- Sec. 537. Research study on the management of breast cancer.

TITLE VI—ENHANCED ACCESS TO HEALTH INSURANCE COVERAGE

- Sec. 601. Carryover of unused benefits from cafeteria plans, flexible spending arrangements, and health flexible spending accounts.
- Sec. 602. Full deduction of health insurance costs for self-employed individuals.
- Sec. 603. Full availability of medical savings accounts.
- Sec. 604. Permitting contribution towards medical savings account through Federal employees health benefits program (FEHBP).

1 **TITLE I—PATIENTS' BILL OF**
 2 **RIGHTS**
 3 **Subtitle A—Right to Advice and**
 4 **Care**

5 **SEC. 101. PATIENT RIGHT TO MEDICAL ADVICE AND CARE.**

6 (a) IN GENERAL.—Part 7 of subtitle B of title I of
 7 the Employee Retirement Income Security Act of 1974
 8 (29 U.S.C. 1185 et seq.) is amended—

1 (1) by redesignating subpart C as subpart D;
2 and

3 (2) by inserting after subpart B the following:

4 **“Subpart C—Patient Right to Medical Advice and**
5 **Care**

6 **“SEC. 721. PATIENT ACCESS TO EMERGENCY MEDICAL**
7 **CARE.**

8 “(a) IN GENERAL.—To the extent that the group
9 health plan provides coverage for benefits consisting of
10 emergency medical care (as defined in subsection (c)), ex-
11 cept for items or services specifically excluded—

12 “(1) the plan shall provide coverage for bene-
13 fits, without requiring preauthorization, for appro-
14 priate emergency medical screening examinations
15 (within the capability of the emergency facility) to
16 the extent that a prudent layperson, who possesses
17 an average knowledge of health and medicine, would
18 determine such examinations to be necessary to de-
19 termine whether emergency medical care (as so de-
20 fined) is necessary, and

21 “(2) the plan shall provide coverage for benefits
22 for additional emergency medical services following
23 an emergency medical screening examination (if de-
24 termined necessary under paragraph (1)) to the ex-
25 tent that a prudent emergency medical professional

1 would determine such additional emergency services
2 to be necessary to avoid the consequences described
3 in paragraph (2) of subsection (c).

4 “(b) UNIFORM COST-SHARING REQUIRED.—Nothing
5 in this section shall be construed as preventing a group
6 health plan from imposing any form of cost-sharing appli-
7 cable to any participant or beneficiary (including coinsur-
8 ance, copayments, deductibles, and any other charges) in
9 relation to coverage for benefits described in subsection
10 (a), if such form of cost-sharing is uniformly applied under
11 such plan, with respect to similarly situated participants
12 and beneficiaries, to all benefits consisting of emergency
13 medical care (as defined in subsection (c)) provided to
14 such similarly situated participants and beneficiaries
15 under the plan.

16 “(c) DEFINITION OF EMERGENCY MEDICAL CARE.—
17 In this section:

18 “(1) IN GENERAL.—The term “emergency med-
19 ical care” means, with respect to a participant or
20 beneficiary under a group health plan, covered inpa-
21 tient and outpatient services that—

22 “(A) are furnished by a provider that is
23 qualified to furnish such services; and

1 “(B) are needed to evaluate or stabilize an
 2 emergency medical condition (as defined in
 3 paragraph (2)).

4 “(2) EMERGENCY MEDICAL CONDITION.—The
 5 term “emergency medical care” means a medical
 6 condition manifesting itself by acute symptoms of
 7 sufficient severity (including severe pain) such that
 8 a prudent layperson, who possesses an average
 9 knowledge of health and medicine, could reasonably
 10 expect the absence of immediate medical attention to
 11 result in—

12 “(A) placing the health of the participant
 13 or beneficiary (or, with respect to a pregnant
 14 woman, the health of the woman or her unborn
 15 child) in serious jeopardy,

16 “(B) serious impairment to bodily func-
 17 tions, or

18 “(C) serious dysfunction of any bodily
 19 organ or part.

20 **“SEC. 722. OFFERING OF CHOICE OF COVERAGE OPTIONS.**

21 “(a) REQUIREMENT.—

22 “(1) OFFERING OF POINT-OF-SERVICE COV-
 23 ERAGE OPTION.—Except as provided in paragraph
 24 (2), if a group health plan provides coverage for ben-
 25 efits only through a defined set of participating

1 health care professionals, the plan shall offer the
 2 participant the option to purchase point-of-service
 3 coverage (as defined in subsection (b)) for all such
 4 benefits for which coverage is otherwise so limited.
 5 Such option shall be made available to the partici-
 6 pant at the time of enrollment under the plan and
 7 at such other times as the plan offers the participant
 8 a choice of coverage options.

9 “(2) EXCEPTION IN THE CASE OF MULTIPLE
 10 ISSUER OR COVERAGE OPTIONS.—Paragraph (1)
 11 shall not apply with respect to a participant in a
 12 group health plan if the plan offers the partici-
 13 pant—

14 “(A) a choice of health insurance coverage
 15 through more than one health insurance issuer;
 16 or

17 “(B) two or more coverage options that
 18 differ significantly with respect to the use of
 19 participating health care professionals or the
 20 networks of such professionals that are used.

21 “(b) POINT-OF-SERVICE COVERAGE DEFINED.—In
 22 this section, the term ‘point-of-service coverage’ means,
 23 with respect to benefits covered under a group health plan,
 24 coverage of such benefits when provided by a nonpartici-
 25 pating health care professional.

1 “(c) SMALL EMPLOYER EXEMPTION.—

2 “(1) IN GENERAL.—This section shall not apply
3 to any group health plan of a small employer.

4 “(2) SMALL EMPLOYER.—For purposes of
5 paragraph (1), the term ‘small employer’ means, in
6 connection with a group health plan with respect to
7 a calendar year and a plan year, an employer who
8 employed an average of at least 2 but not more than
9 50 employees on business days during the preceding
10 calendar year and who employs at least 2 employees
11 on the first day of the plan year. For purposes of
12 this paragraph, the provisions of subparagraph (C)
13 of section 712(c)(1) shall apply in determining em-
14 ployer size.

15 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
16 tion shall be construed—

17 “(1) as requiring coverage for benefits for a
18 particular type of health care professional;

19 “(2) as requiring an employer to pay any costs
20 as a result of this section or to make equal contribu-
21 tions with respect to different health coverage op-
22 tions;

23 “(3) as preventing a group health plan from
24 imposing higher premiums or cost-sharing on a par-

1 ticipant for the exercise of a point-of-service cov-
 2 erage option; or

3 “(4) to require that a group health plan include
 4 coverage of health care professionals that the plan
 5 excludes because of fraud, quality of care, or other
 6 similar reasons with respect to such professionals.

7 **“SEC. 723. PATIENT ACCESS TO OBSTETRIC AND GYNECO-**
 8 **LOGICAL CARE.**

9 “(a) IN GENERAL.—In any case in which a group
 10 health plan—

11 “(1) provides coverage for benefits consisting
 12 of—

13 “(A) gynecological care (such as preventive
 14 women’s health examinations); or

15 “(B) obstetric care (such as pregnancy-re-
 16 lated services);

17 provided by a participating physician who specializes
 18 in such care; and

19 “(2) requires or provides for designation by a
 20 participant or beneficiary of a participating primary
 21 care provider;

22 if the primary care provider designated by such a partici-
 23 pant or beneficiary is not such a physician as described
 24 in paragraph (1), then the plan shall meet the require-
 25 ments of subsection (b).

1 “(b) REQUIREMENTS.—A group health plan meets
2 the requirements of this subsection, in connection with the
3 coverage of benefits described in subsection (a) consisting
4 of care described in subparagraph (A) or (B) of subsection
5 (a)(1), if the plan—

6 “(1) does not require authorization or a referral
7 by the primary care provider in order to obtain cov-
8 erage for such benefits, and

9 “(2) treats the ordering of other routine care of
10 the same type, by the participating physician provid-
11 ing the care described in subparagraph (A) or (B)
12 of subsection (a)(1), as the authorization of the pri-
13 mary care provider with respect to such care.

14 “(c) RULE OF CONSTRUCTION.—Nothing in sub-
15 section (b)(2) shall waive any requirements of coverage re-
16 lating to medical necessity or appropriateness with respect
17 to coverage of gynecological or obstetric care so ordered.

18 **“SEC. 724. PATIENT ACCESS TO PEDIATRIC CARE.**

19 “(a) IN GENERAL.—In any case in which a group
20 health plan—

21 “(1) provides coverage for benefits consisting of
22 pediatric care by a participating pediatrician; and

23 “(2) requires or provides for designation by a
24 participant or beneficiary of a participating primary
25 care provider;

1 if the primary care provider designated by such a partici-
 2 pant or beneficiary is not a physician as described in para-
 3 graph (1), then the plan shall meet the requirements of
 4 subsection (b).

5 “(b) REQUIREMENTS.—A group health plan meets
 6 the requirements of this subsection, in connection with the
 7 coverage of benefits described in subsection (a) consisting
 8 of care described in subsection (a)(1), if the plan—

9 “(1) does not require authorization or a referral
 10 by the primary care provider in order to obtain cov-
 11 erage for such benefits, and

12 “(2) treats the ordering of other routine care of
 13 the same type, by the participating physician provid-
 14 ing the care described in subsection (a)(1), as the
 15 authorization of the primary care provider with re-
 16 spect to such care.

17 “(c) CONSTRUCTION.—Nothing in subsection (b)(2)
 18 shall waive any requirements of coverage relating to medi-
 19 cal necessity or appropriateness with respect to coverage
 20 of pediatric care so ordered.

21 **“SEC. 725. CONTINUITY OF CARE.**

22 “(a) IN GENERAL.—

23 “(1) TERMINATION OF PROVIDER.—If a con-
 24 tract between a group health plan and a health care
 25 provider is terminated (as defined in paragraph (2)),

1 or benefits or coverage provided by a health care
 2 provider are terminated because of a change in the
 3 terms of provider participation in a group health
 4 plan, and an individual who is a participant or bene-
 5 ficiary in the plan is undergoing a course of treat-
 6 ment from the provider at the time of such termi-
 7 nation, the plan shall—

8 “(A) notify the individual on a timely basis
 9 of such termination, and

10 “(B) in the case of termination described
 11 in paragraph (2), (3), or (4) of subsection (b),
 12 and subject to subsection (c), permit the indi-
 13 vidual to continue or be covered with respect
 14 to the course of treatment with the provider’s
 15 consent during a transitional period (as pro-
 16 vided under subsection (b)).

17 “(2) TERMINATION.—In this section, the term
 18 ‘terminated’ includes, with respect to a contract, the
 19 expiration or nonrenewal of the contract by the
 20 group health plan, but does not include a termi-
 21 nation of the contract by the plan for failure to meet
 22 applicable quality standards or for fraud.

23 “(b) TRANSITIONAL PERIOD.—

24 “(1) GENERAL RULE.—Except as provided in
 25 paragraph (3), the transitional period under this

1 subsection shall extend for up to 90 days from the
2 date of the notice described in subsection (a)(1)(A)
3 of the provider's termination.

4 “(2) INSTITUTIONAL CARE.—Subject to para-
5 graph (1), the transitional period under this sub-
6 section for institutional or inpatient care from a pro-
7 vider shall extend until the discharge or termination
8 of the period of institutionalization and also shall in-
9 clude institutional care provided within a reasonable
10 time of the date of termination of the provider sta-
11 tus if the care was scheduled before the date of the
12 announcement of the termination of the provider
13 status under subsection (a)(1)(A) or if the individual
14 on such date was on an established waiting list or
15 otherwise scheduled to have such care.

16 “(3) PREGNANCY.—Notwithstanding paragraph
17 (1), if—

18 “(A) a participant or beneficiary has en-
19 tered the second trimester of pregnancy at the
20 time of a provider's termination of participa-
21 tion; and

22 “(B) the provider was treating the preg-
23 nancy before the date of the termination;
24 the transitional period under this subsection with re-
25 spect to provider's treatment of the pregnancy shall

1 extend through the provision of post-partum care di-
2 rectly related to the delivery.

3 “(4) TERMINAL ILLNESS.—Subject to para-
4 graph (1), if—

5 “(A) a participant or beneficiary was de-
6 termined to be terminally ill (as determined
7 under section 1861(dd)(3)(A) of the Social Se-
8 curity Act) prior to a provider’s termination of
9 participation; and

10 “(B) the provider was treating the termi-
11 nal illness before the date of termination;
12 the transitional period under this subsection shall
13 extend for the remainder of the individual’s life for
14 care directly related to the treatment of the terminal
15 illness.

16 “(c) PERMISSIBLE TERMS AND CONDITIONS.—A
17 group health plan may condition coverage of continued
18 treatment by a provider under subsection (a)(1)(B) upon
19 the provider agreeing to the following terms and condi-
20 tions:

21 “(1) The provider agrees to accept reimburse-
22 ment from the plan and individual involved (with re-
23 spect to cost-sharing) at the rates applicable prior to
24 the start of the transitional period as payment in
25 full (or, in the case described in subsection (b)(2),

1 at the rates applicable under the replacement plan
2 after the date of the termination of the contract with
3 the group health plan) and not to impose cost-shar-
4 ing with respect to the individual in an amount that
5 would exceed the cost-sharing that could have been
6 imposed if the contract referred to in subsection
7 (a)(1) had not been terminated.

8 “(2) The provider agrees to adhere to the qual-
9 ity assurance standards of the plan responsible for
10 payment under paragraph (1) and to provide to such
11 plan necessary medical information related to the
12 care provided.

13 “(3) The provider agrees otherwise to adhere to
14 such plan’s policies and procedures, including proce-
15 dures regarding referrals and obtaining prior au-
16 thorization and providing services pursuant to a
17 treatment plan (if any) approved by the plan.

18 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
19 tion shall be construed to require the coverage of benefits
20 which would not have been covered if the provider involved
21 remained a participating provider.

22 “(e) DEFINITION.—In this section, the term ‘health
23 care provider’ or ‘provider’ means—

24 “(1) any individual who is engaged in the deliv-
25 ery of health care services in a State and who is re-

1 quired by State law or regulation to be licensed or
 2 certified by the State to engage in the delivery of
 3 such services in the State; and

4 “(2) any entity that is engaged in the delivery
 5 of health care services in a State and that, if it is
 6 required by State law or regulation to be licensed or
 7 certified by the State to engage in the delivery of
 8 such services in the State, is so licensed.

9 **“SEC. 726. PROTECTION OF PATIENT-PROVIDER COMMU-**
 10 **NICATIONS.**

11 “(a) IN GENERAL.—Subject to subsection (b), a
 12 group health plan (in relation to a participant or bene-
 13 ficiary) shall not prohibit a health care professional from
 14 advising such a participant or beneficiary who is a patient
 15 of the professional about the health status of the partici-
 16 pant or beneficiary or medical care or treatment for the
 17 condition or disease of the participant or beneficiary, re-
 18 gardless of whether coverage for such care or treatment
 19 are provided under the contract, if the professional is act-
 20 ing within the lawful scope of practice.

21 “(b) RULE OF CONSTRUCTION.—Nothing in this sec-
 22 tion shall be construed as requiring a group health plan
 23 to provide specific benefits under the terms of such plan.

1 **“SEC. 727. GENERALLY APPLICABLE PROVISIONS.**

2 “(a) **APPLICABILITY.**—The provisions of this subpart
3 shall apply to group health plans. Such provisions shall
4 not apply to a health insurance issuer that is licensed by
5 a State and subject to State laws that regulate insurance
6 within the meaning of section 514(b)(2), while engaged
7 in the business of insurance in such State.

8 “(b) **TREATMENT OF MULTIPLE COVERAGE OP-**
9 **TIONS.**—In the case of a group health plan that provides
10 benefits under 2 or more coverage options, the require-
11 ments of sections 721, 723, 724, 725 and 726 shall apply
12 separately with respect to each coverage option.”.

13 (b) **RULE WITH RESPECT TO CERTAIN PLANS.**—

14 (1) **IN GENERAL.**—Notwithstanding any other
15 provision of law, health insurance issuers may offer,
16 and eligible individuals may purchase, high deduct-
17 ible health plans described in section 220(c)(2)(A) of
18 the Internal Revenue Code of 1986. Effective for the
19 4-year period beginning on the date of the enact-
20 ment of this Act, such health plans shall not be re-
21 quired to provide payment for any health care items
22 or services that are exempt from the plan’s deduct-
23 ible.

24 (2) **EXISTING STATE LAWS.**—A State law relat-
25 ing to payment for health care items and services in
26 effect on the date of enactment of this Act that is

1 preempted under paragraph (1), shall not apply to
 2 high deductible health plans after the expiration of
 3 the 4-year period described in such paragraph unless
 4 the State reenacts such law after such period.

5 (c) CONFORMING AMENDMENT.—The table of con-
 6 tents in section 1 of such Act is amended—

7 (1) in the item relating to subpart C, by strik-
 8 ing “Subpart C” and inserting “Subpart D”; and

9 (2) by adding at the end of the items relating
 10 to subpart B of part 7 of subtitle B of title I of such
 11 Act the following new items:

“SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

“Sec. 721. Patient access to emergency medical care.

“Sec. 722. Offering of choice of coverage options.

“Sec. 723. Patient access to obstetric and gynecological care.

“Sec. 724. Patient access to pediatric care.

“Sec. 725. Continuity of care.

“Sec. 726. Protection of patient-provider communications.

“Sec. 727. Generally applicable provisions.”.

12 **SEC. 102. EFFECTIVE DATE AND RELATED RULES.**

13 (a) IN GENERAL.—The amendments made by this
 14 subtitle shall apply with respect to plan years beginning
 15 on or after January 1 of the second calendar year follow-
 16 ing the date of the enactment of this Act. The Secretary
 17 shall issue all regulations necessary to carry out the
 18 amendments made by this section before the effective date
 19 thereof.

20 (b) LIMITATION ON ENFORCEMENT ACTIONS.—No
 21 enforcement action shall be taken, pursuant to the amend-

ments made by this subtitle, against a group health plan with respect to a violation of a requirement imposed by such amendments before the date of issuance of regulations issued in connection with such requirement, if the plan has sought to comply in good faith with such requirement.

Subtitle B—Right to Information About Plans and Providers

SEC. 111. INFORMATION ABOUT PLANS.

(a) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is amended by adding at the end the following:

“SEC. 713. HEALTH PLAN COMPARATIVE INFORMATION.

“(a) REQUIREMENT.—A group health plan, or health insurance issuer in connection with group health insurance coverage, shall, not later than 12 months after the date of enactment of this section, provide for the disclosure, in a clear and accurate form to each enrollee, or upon request to a potential enrollee eligible to receive benefits under the plan, or plan sponsor with which the plan or issuer has contracted, of the information described in subsection (b).

1 “(b) REQUIRED INFORMATION.—The informational
2 materials to be distributed under this section shall include
3 for each health benefit plan the following:

4 “(1) A description of the covered items and
5 services under each such plan and any in- and out-
6 of-network features of each such plan.

7 “(2) A description of any cost-sharing, includ-
8 ing premiums, deductibles, coinsurance, and copay-
9 ment amounts, for which the enrollee will be respon-
10 sible, including any annual or lifetime limits on ben-
11 efits, for each such plan.

12 “(3) A description of any optional supplemental
13 benefits offered by each such plan and the terms
14 and conditions (including premiums or cost-sharing)
15 for such supplemental coverage.

16 “(4) A description of any restrictions on pay-
17 ments for services furnished to an enrollee by a
18 health care professional that is not a participating
19 professional and the liability of the enrollee for addi-
20 tional payments for these services.

21 “(5) A description of the service area of each
22 such plan, including the provision of any out-of-area
23 coverage.

24 “(6) A description of the extent to which enroll-
25 ees may select the primary care provider of their

1 choice, including providers both within the network
2 and outside the network of each such plan (if the
3 plan permits out-of-network services).

4 “(7) A description of the procedures for ad-
5 vance directives and organ donation decisions if the
6 plan maintains such procedures.

7 “(8) A description of the requirements and pro-
8 cedures to be used to obtain preauthorization for
9 health services (including telephone numbers and
10 mailing addresses), including referrals for specialty
11 care.

12 “(9) A summary of the rules and methods for
13 appealing coverage decisions and filing grievances
14 (including telephone numbers and mailing address-
15 es), as well as other available remedies.

16 “(10) A summary of the rules for access to
17 emergency room care. Also, any available edu-
18 cational material regarding proper use of emergency
19 services.

20 “(11) A description of whether or not coverage
21 is provided for experimental treatments, investiga-
22 tional treatments, or clinical trials and the cir-
23 cumstances under which access to such treatments
24 or trials is made available.

1 “(12) A description of the specific preventative
2 services covered under the plan if such services are
3 covered.

4 “(13) A statement that the following informa-
5 tion, and instructions on obtaining such information
6 (including telephone numbers and, if available,
7 Internet websites), shall be made available upon re-
8 quest:

9 “(A) The names, addresses, telephone
10 numbers, and State licensure status of the
11 plan’s participating health care professionals
12 and participating health care facilities, and, if
13 available, the education, training, speciality
14 qualifications or certifications of such profes-
15 sionals.

16 “(B) A summary description of the meth-
17 ods used for compensating participating health
18 care professionals, such as capitation, fee-for-
19 service, salary, or a combination thereof. The
20 requirement of this subparagraph shall not be
21 construed as requiring plans to provide infor-
22 mation concerning proprietary payment meth-
23 odology.

24 “(C) A summary description of the meth-
25 ods used for compensating health care facilities,

1 including per diem, fee-for-service, capitation,
2 bundled payments, or a combination thereof.
3 The requirement of this subparagraph shall not
4 be construed as requiring plans to provide in-
5 formation concerning proprietary payment
6 methodology.

7 “(D) A summary description of the proce-
8 dures used for utilization review.

9 “(E) The list of the specific prescription
10 medications included in the formulary of the
11 plan, if the plan uses a defined formulary, and
12 any provision for obtaining off-formulary medi-
13 cations.

14 “(F) A description of the specific exclu-
15 sions from coverage under the plan.

16 “(G) Any available information related to
17 the availability of translation or interpretation
18 services for non-English speakers and people
19 with communication disabilities, including the
20 availability of audio tapes or information in
21 Braille.

22 “(H) Any information that is made public
23 by accrediting organizations in the process of
24 accreditation if the plan is accredited, or any

1 additional quality indicators that the plan
2 makes available.

3 “(c) MANNER OF DISTRIBUTION.—

4 “(1) IN GENERAL.—The information described
5 in this section shall be distributed in an accessible
6 format that is understandable to an average plan en-
7 rollee.

8 “(2) RULE OF CONSTRUCTION.—For purposes
9 of this section, a group health plan, or health insur-
10 ance issuer in connection with group health insur-
11 ance coverage, in reliance on records maintained by
12 the plan or issuer, shall be deemed to have met the
13 requirements of this section if the plan or issuer pro-
14 vides the information requested under this section—

15 “(A) in the case of the plan, to partici-
16 pants and beneficiaries at the address contained
17 in such records with respect to such partici-
18 pants and beneficiaries; or

19 “(B) in the case of the issuer, to the em-
20 ployer of a participant if the employer provides
21 for the coverage of such participant under the
22 plan involved or to participants and bene-
23 ficiaries at the address contained in such
24 records with respect to such participants and
25 beneficiaries.

1 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
 2 tion may be construed to prohibit a group health plan,
 3 or health insurance issuer in connection with group health
 4 insurance coverage, from distributing any other additional
 5 information determined by the plan or issuer to be impor-
 6 tant or necessary in assisting participants and bene-
 7 ficiaries enrollees or upon request potential participants
 8 in the selection of a health plan or from providing informa-
 9 tion under subsection (b)(13) as part of the required infor-
 10 mation.

11 “(e) HEALTH CARE PROFESSIONAL.—In this section,
 12 the term ‘health care professional’ means a physician (as
 13 defined in section 1861(r) of the Social Security Act) or
 14 other health care professional if coverage for the profes-
 15 sional’s services is provided under the health plan involved
 16 for the services of the professional. Such term includes a
 17 podiatrist, optometrist, chiropractor, psychologist, dentist,
 18 physician assistant, physical or occupational therapist and
 19 therapy assistant, speech-language pathologist, audiol-
 20 ogist, registered or licensed practical nurse (including
 21 nurse practitioner, clinical nurse specialist, certified reg-
 22 istered nurse anesthetist, and certified nurse-midwife), li-
 23 censed certified social worker, registered respiratory thera-
 24 pist, and certified respiratory therapy technician.”.

25 (b) CONFORMING AMENDMENTS.—

1 (1) Section 732(a) of the Employee Retirement
 2 Income Security Act of 1974 (29 U.S.C. 1185(a)) is
 3 amended by striking “section 711, and inserting
 4 “sections 711 and 713”.

5 (2) The table of contents in section 1 of the
 6 Employee Retirement Income Security Act of 1974
 7 (29 U.S.C. 1001) is amended by inserting after the
 8 item relating to section 712, the following:
 “Sec. 713. Health plan comparative information.”.

9 **SEC. 112. INFORMATION ABOUT PROVIDERS.**

10 (a) STUDY.—The Secretary of Health and Human
 11 Services shall enter into a contract with the Institute of
 12 Medicine for the conduct of a study, and the submission
 13 to the Secretary of a report, that includes—

14 (1) an analysis of information concerning health
 15 care professionals that is currently available to pa-
 16 tients, consumers, States, and professional societies,
 17 nationally and on a State-by-State basis, including
 18 patient preferences with respect to information
 19 about such professionals and their competencies;

20 (2) an evaluation of the legal and other barriers
 21 to the sharing of information concerning health care
 22 professionals; and

23 (3) recommendations for the disclosure of infor-
 24 mation on health care professionals, including the
 25 competencies and professional qualifications of such

1 practitioners, to better facilitate patient choice, qual-
 2 ity improvement, and market competition.

3 (b) REPORT.—Not later than 18 months after the
 4 date of enactment of this Act, the Secretary of Health and
 5 Human Services shall forward to the appropriate commit-
 6 tees of Congress a copy of the report and study conducted
 7 under subsection (a).

8 **Subtitle C—Right to Hold Health** 9 **Plans Accountable**

10 **SEC. 121. AMENDMENT TO EMPLOYEE RETIREMENT IN-** 11 **COME SECURITY ACT OF 1974.**

12 (a) IN GENERAL.—Section 503 of the Employee Re-
 13 tirement Income Security Act of 1974 (29 U.S.C. 1133)
 14 is amended to read as follows:

15 **“SEC. 503. CLAIMS PROCEDURE, COVERAGE DETERMINA-** 16 **TION, GRIEVANCES AND APPEALS.**

17 “(a) CLAIMS PROCEDURE.—In accordance with regu-
 18 lations of the Secretary, every employee benefit plan
 19 shall—

20 “(1) provide adequate notice in writing to any
 21 participant or beneficiary whose claim for benefits
 22 under the plan has been denied, setting forth the
 23 specific reasons for such denial, written in a manner
 24 calculated to be understood by the participant, and

1 “(2) afford a reasonable opportunity to any
 2 participant whose claim for benefits has been denied
 3 for a full and fair review by the appropriate named
 4 fiduciary of the decision denying the claim.

5 “(b) COVERAGE DETERMINATIONS UNDER GROUP
 6 HEALTH PLANS.—

7 “(1) PROCEDURES.—

8 “(A) IN GENERAL.—A group health plan
 9 or health insurance issuer conducting utilization
 10 review shall ensure that procedures are in place
 11 for—

12 “(i) making determinations regarding
 13 whether an enrollee is eligible to receive a
 14 payment or coverage for health services
 15 under the plan or coverage involved and
 16 any cost-sharing amount that the enrollee
 17 is required to pay with respect to such
 18 service;

19 “(ii) notifying covered enrollees (or
 20 the legal representative of such enrollees)
 21 and the treating health care professionals
 22 involved regarding determinations made
 23 under the plan or issuer and any addi-
 24 tional payments that the enrollee may be

1 required to make with respect to such serv-
 2 ice; and

3 “(iii) responding to requests, either
 4 written or oral, for coverage determina-
 5 tions or for internal appeals from an en-
 6 rollee (or the legal representative of such
 7 enrollee) or the treating health care profes-
 8 sional.

9 “(B) ORAL REQUESTS.—With respect to
 10 an oral request described in subparagraph
 11 (A)(iii), a group health plan or health insurance
 12 issuer may require that the requesting individ-
 13 ual provide written evidence of such request.

14 “(2) TIMELINE FOR MAKING DETERMINA-
 15 TIONS.—

16 “(A) ROUTINE DETERMINATION.—A group
 17 health plan or a health insurance issuer shall
 18 maintain procedures to ensure that prior au-
 19 thorization determinations concerning the provi-
 20 sion of non-emergency items or services are
 21 made within 30 days from the date on which
 22 the request for a determination is submitted,
 23 except that such period may be extended where
 24 certain circumstances exist that are determined

1 by the Secretary to be beyond control of the
2 plan or issuer.

3 “(B) EXPEDITED DETERMINATION.—

4 “(i) IN GENERAL.—A prior authoriza-
5 tion determination under this subsection
6 shall be made within 72 hours after a re-
7 quest is received by the plan or issuer
8 under clause (ii) or (iii).

9 “(ii) REQUEST BY ENROLLEE.—A
10 plan or issuer shall maintain procedures
11 for expediting a prior authorization deter-
12 mination under this subsection upon the
13 request of an enrollee if, based on such a
14 request, the plan or issuer determines that
15 the normal time for making such a deter-
16 mination could seriously jeopardize the life
17 or health of the enrollee.

18 “(iii) DOCUMENTATION BY HEALTH
19 CARE PROFESSIONAL.—A plan or issuer
20 shall maintain procedures for expediting a
21 prior authorization determination under
22 this subsection if the request involved indi-
23 cates that the treating health care profes-
24 sional has documented, based on the medi-
25 cal exigencies, that a determination under

1 the procedures described in subparagraph
2 (A) could seriously jeopardize the life or
3 health of the enrollee.

4 “(C) CONCURRENT DETERMINATIONS.—A
5 plan or issuer shall maintain procedures to cer-
6 tify or deny coverage of an extended stay or ad-
7 ditional services.

8 “(D) RETROSPECTIVE DETERMINATION.—
9 A plan or issuer shall maintain procedures to
10 ensure that, with respect to the retrospective re-
11 view of a determination made under paragraph
12 (1), the determination shall be made within 30
13 working days of the date on which the plan or
14 issuer receives all necessary information.

15 “(3) NOTICE OF DETERMINATIONS.—

16 “(A) ROUTINE DETERMINATION.—With re-
17 spect to a coverage determination of a plan or
18 issuer under paragraph (2)(A), the plan or
19 issuer shall issue notice of such determination
20 to the enrollee (or the legal representative of
21 the enrollee), and consistent with the medical
22 exigencies of the case, to the treating health
23 care professional involved not later than 2
24 working days after the date on which the deter-
25 mination is made.

1 “(B) EXPEDITED DETERMINATION.—With
2 respect to a coverage determination of a plan or
3 issuer under paragraph (2)(B), the plan or
4 issuer shall issue notice of such determination
5 to the enrollee (or the legal representative of
6 the enrollee), and consistent with the medical
7 exigencies of the case, to the treating health
8 care professional involved within the 72 hour
9 period described in paragraph (2)(B).

10 “(C) CONCURRENT REVIEWS.—With re-
11 spect to the determination under a plan or
12 issuer under paragraph (1) to certify or deny
13 coverage of an extended stay or additional serv-
14 ices, the plan or issuer shall issue notice of such
15 determination to the treating health care pro-
16 fessional and to the enrollee involved (or the
17 legal representative of the enrollee) within 1
18 working day of the date on which the initial no-
19 tice was issued.

20 “(D) RETROSPECTIVE REVIEWS.—With re-
21 spect to the retrospective review under a plan
22 or issuer of a determination made under para-
23 graph (1), a determination shall be made within
24 30 working days of the date on which the plan
25 or issuer receives all necessary information. The

1 plan or issuer shall issue written notice of an
 2 approval or disapproval of a determination
 3 under this subparagraph to the enrollee (or the
 4 legal representative of the enrollee) and health
 5 care provider involved within 5 working days of
 6 the date on which such determination is made.

7 “(E) REQUIREMENTS OF NOTICE OF AD-
 8 VERSE COVERAGE DETERMINATIONS.—A writ-
 9 ten or electronic notice of an adverse coverage
 10 determination under this subsection, or of an
 11 expedited adverse coverage determination under
 12 paragraph (2)(B), shall be provided to the en-
 13 rollee (or the legal representative of the en-
 14 rollee) and treating health care professional (if
 15 any) involved and shall include—

16 “(i) the reasons for the determination
 17 (including the clinical or scientific-evidence
 18 based rationale used in making the deter-
 19 mination) written in a manner to be under-
 20 standable to the average enrollee;

21 “(ii) the procedures for obtaining ad-
 22 ditional information concerning the deter-
 23 mination; and

24 “(iii) notification of the right to ap-
 25 peal the determination and instructions on

1 how to initiate an appeal in accordance
2 with subsection (d).

3 “(c) GRIEVANCES.—A group health plan or a health
4 insurance issuer shall have written procedures for address-
5 ing grievances between the plan and enrollees. Determina-
6 tions under such procedures shall be non-appealable.

7 “(d) INTERNAL APPEAL OF COVERAGE DETERMINA-
8 TIONS.—

9 “(1) IN GENERAL.—An enrollee (or the legal
10 representative of the enrollee) and the treating
11 health care professional with the consent of the en-
12 rollee (or the legal representative of the enrollee),
13 may appeal any adverse coverage determination
14 under subsection (b) under the procedures described
15 in this subsection.

16 “(2) RECORDS.—A group health plan and a
17 health insurance issuer shall maintain written
18 records, for at least 6 years, with respect to any ap-
19 peal under this subsection for purposes of internal
20 quality assurance and improvement.

21 “(3) ROUTINE DETERMINATIONS.—A group
22 health plan or a health insurance issuer shall provide
23 for the consideration of an appeal of an adverse rou-
24 tine determination under this subsection not later

1 than 30 working days after the date on which a re-
2 quest for such appeal is received.

3 “(4) EXPEDITED DETERMINATION.—

4 “(A) IN GENERAL.—An expedited deter-
5 mination with respect to an appeal under this
6 subsection shall be made in accordance with the
7 medical exigencies of the case, but in no case
8 more than 72 hours after the request for such
9 appeal is received by the plan or issuer under
10 subparagraph (B) or (C).

11 “(B) REQUEST BY ENROLLEE.—A plan or
12 issuer shall maintain procedures for expediting
13 a prior authorization determination under this
14 subsection upon the request of an enrollee if,
15 based on such a request, the plan or issuer de-
16 termines that the normal time for making such
17 a determination could seriously jeopardize the
18 life or health of the enrollee.

19 “(C) DOCUMENTATION BY HEALTH CARE
20 PROFESSIONAL.—A plan or issuer shall main-
21 tain procedures for expediting a prior author-
22 ization determination under this subsection if
23 the request involved indicates that the treating
24 health care professional has documented, based
25 on the medical exigencies that a determination

1 under the procedures described in paragraph
2 (2) could seriously jeopardize the life or health
3 of the enrollee.

4 “(5) CONDUCT OF REVIEW.—A review of an ad-
5 verse coverage determination under this subsection
6 shall be conducted by an individual with appropriate
7 expertise who was not involved in the initial deter-
8 mination.

9 “(6) LACK OF MEDICAL NECESSITY.—An ap-
10 peal under this subsection relating to a determina-
11 tion to deny coverage based on a lack of medical ne-
12 cessity or appropriateness, or based on an experi-
13 mental or investigational treatment, shall be made
14 only by a physician with appropriate expertise in the
15 field of medicine involved who was not involved in
16 the initial determination.

17 “(7) NOTICE.—

18 “(A) IN GENERAL.—Written notice of a
19 determination made under an internal review
20 process shall be issued to the enrollee (or the
21 legal representative of the enrollee) and the
22 treating health care professional not later than
23 2 working days after the completion of the re-
24 view (or within the 72-hour period referred to
25 in paragraph (4) if applicable).

1 “(B) ADVERSE COVERAGE DETERMINA-
 2 TIONS.—With respect to an adverse coverage
 3 determination made under this subsection, the
 4 notice described in subparagraph (A) shall in-
 5 clude—

6 “(i) the reasons for the determination
 7 (including the clinical or scientific-evidence
 8 based rationale used in making the deter-
 9 mination) written in a manner to be under-
 10 standable to the average enrollee;

11 “(ii) the procedures for obtaining ad-
 12 ditional information concerning the deter-
 13 mination; and

14 “(iii) notification of the right to an
 15 external review under subsection (e) and
 16 instructions on how to initiate such a re-
 17 view.

18 “(e) EXTERNAL REVIEW.—

19 “(1) IN GENERAL.—A group health plan or a
 20 health insurance issuer shall have written procedures
 21 to permit an enrollee (or the legal representative of
 22 the enrollee) access to an external review with re-
 23 spect to a coverage determination concerning a par-
 24 ticular item or service where the plan, in consulta-

1 tion with the plan’s legal representative, has deter-
 2 mined that—

3 “(A) the particular item or service in-
 4 volved, when medically appropriate and nec-
 5 essary, is generally a covered benefit under the
 6 terms and conditions of the contract between
 7 the plan or issuer and the enrollee;

8 “(B) the coverage determination involved
 9 denied coverage for such item or service because
 10 the provision of such item or service—

11 “(i) does not meet the plan’s or
 12 issuer’s requirements for medical appro-
 13 priateness or necessity and the amount in-
 14 volved exceeds \$1,000; or

15 “(ii) would constitute experimental or
 16 investigational treatment and there is a
 17 significant risk of placing the life or health
 18 of the enrollee in jeopardy; and

19 “(C) the enrollee has completed the inter-
 20 nal appeals process with respect to such deter-
 21 mination.

22 “(2) INITIATION OF THE EXTERNAL REVIEW
 23 PROCESS.—

24 “(A) FILING OF REQUEST.—An enrollee
 25 (or the legal representative of the enrollee) who

1 desires to have an external review conducted
2 under this subsection shall file a written request
3 for such a review with the plan or issuer in-
4 volved not later than 30 working days after the
5 receipt of a final denial of a claim under sub-
6 section (d). Any such request shall include the
7 consent of the enrollee (or the legal representa-
8 tive of the enrollee) for the release of medical
9 information and records to external reviewers
10 regarding the enrollee if such information is
11 necessary for the proper conduct of the external
12 review.

13 “(B) INFORMATION AND NOTICE.—Not
14 later than 5 working days after the receipt of
15 a request under subparagraph (A), the plan or
16 issuer involved shall select an external appeals
17 entity under paragraph (3)(A) that shall be re-
18 sponsible for designating an external reviewer
19 under paragraph (3)(B).

20 “(C) PROVISION OF INFORMATION.—The
21 plan or issuer involved shall forward all nec-
22 essary information (including medical records,
23 any relevant review criteria, the clinical ration-
24 ale consistent with the terms and conditions of
25 the contract between the plan or issuer and the

1 enrollee for the coverage denial, and evidence of
 2 the enrollee’s coverage) to the external reviewer
 3 selected under paragraph (3)(B).

4 “(D) NOTIFICATION.—The plan or issuer
 5 involved shall send a written notification to the
 6 enrollee (or the legal representative of the en-
 7 rollee) and the plan administrator, indicating
 8 that an external review has been initiated.

9 “(3) CONDUCT OF EXTERNAL REVIEW.—

10 “(A) DESIGNATION OF EXTERNAL AP-
 11 PEALS ENTITY BY PLAN OR ISSUER.—A plan or
 12 issuer that receives a request for an external re-
 13 view under paragraph (2)(A) shall designate
 14 one of the following entities to serve as the ex-
 15 ternal appeals entity:

16 “(i) An external review entity licensed
 17 or credentialed by a State.

18 “(ii) A State agency established for
 19 the purpose of conducting independent ex-
 20 ternal reviews.

21 “(iii) Any entity under contract with
 22 the Federal Government to provide exter-
 23 nal review services.

24 “(iv) Any entity accredited as an ex-
 25 ternal review entity by an accrediting body

1 recognized by the Secretary for such pur-
 2 pose.

3 “(v) Any fully accredited teaching
 4 hospital.

5 “(vi) Any other entity meeting criteria
 6 established by the Secretary for purposes
 7 of this subparagraph.

8 “(B) DESIGNATION OF EXTERNAL RE-
 9 VIEWER BY EXTERNAL APPEALS ENTITY.—The
 10 external appeals entity designated under sub-
 11 paragraph (A) shall designate one or more indi-
 12 viduals to serve as external reviewers with re-
 13 spect to a request receives under paragraph
 14 (2)(A). Such reviewers shall be independent
 15 medical experts who shall—

16 “(i) be appropriately credentialed or
 17 licensed in any State to deliver health care
 18 services;

19 “(ii) not have any material, profes-
 20 sional, familial, or financial affiliation with
 21 the case under review, the enrollee in-
 22 volved, the treating health care profes-
 23 sional, the institution where the treatment
 24 would take place, or the manufacturer or
 25 any drug, device, procedure, or other ther-

1 apy proposed for the enrollee whose treat-
2 ment is under review;

3 “(iii) be experts in the treatment of
4 the enrollee’s medical condition and knowl-
5 edgeable about the recommended therapy;

6 “(iv) receive only reasonable and cus-
7 tomary compensation from the group
8 health plan or health insurance issuer in
9 connection with the external review that is
10 not contingent on the decision rendered by
11 the reviewer; and

12 “(v) not be held liable for decisions re-
13 garding medical determinations (but may
14 be held liable for actions that are arbitrary
15 and capricious).

16 “(4) STANDARD OF REVIEW.—

17 “(A) IN GENERAL.—An external reviewer
18 shall—

19 “(i) make a determination based on
20 the medical necessity, appropriateness, ex-
21 perimental or investigational nature of the
22 coverage denial;

23 “(ii) take into consideration any evi-
24 dence-based decision making or clinical
25 practice guidelines used by the group

1 health plan or health insurance issuer in
2 conducting utilization review; or

3 “(iii) submit a report on the final de-
4 terminations of the review involved to—

5 “(I) the plan or issuer involved;

6 “(II) the enrollee involved (or the
7 legal representative of the enrollee);
8 and

9 “(III) the health care profes-
10 sional involved.

11 “(B) NOTICE.—The plan or issuer involved
12 shall ensure that the enrollee receives notice,
13 within 30 days after the determination of the
14 independent medical expert, regarding the ac-
15 tions of the plan or issuer with respect to the
16 determination of such expert under the external
17 review.

18 “(5) TIMEFRAME FOR REVIEW.—An external
19 reviewer shall complete a review of an adverse cov-
20 erage determination in accordance with the medical
21 exigencies of the case, but in no case later than 30
22 working days after the later of—

23 “(A) the date on which such reviewer is
24 designated; or

1 “(B) the date on which all information
2 necessary to completing such review is received.

3 “(6) BINDING DETERMINATION.—The deter-
4 mination of an external reviewer under this sub-
5 section shall be binding upon the plan or issuer if
6 the provisions of this subsection or the procedures
7 implemented under such provisions were complied
8 with by the external reviewer.

9 “(7) STUDY.—Not later than 2 years after the
10 date of enactment of this section, the General Ac-
11 counting Office shall conduct a study of a statis-
12 tically appropriate sample of completed external re-
13 views. Such study shall include an assessment of the
14 process involved during an external review and the
15 basis of decisionmaking by the external reviewer.
16 The results of such study shall be submitted to the
17 appropriate committees of Congress.

18 “(8) CONTINUING LEGAL RIGHTS OF ENROLL-
19 EES.—Nothing in this section shall be construed as
20 removing any legal rights of participants, bene-
21 ficiaries, enrollees, and others under State or Fed-
22 eral law, including the right to file judicial actions
23 to enforce rights.

24 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
25 tion shall be construed to prohibit a plan administrator

1 or plan fiduciary or health plan medical director from re-
 2 questing an external review by an external reviewer with-
 3 out first completing the internal review process.

4 “(g) DEFINITIONS.—In this section:

5 “(1) ADVERSE COVERAGE DETERMINATION.—

6 The term ‘adverse coverage determination’ means a
 7 coverage determination under the plan which results
 8 in a denial of coverage or reimbursement.

9 “(2) COVERAGE DETERMINATION.—The term

10 ‘coverage determination’ means with respect to items
 11 and services for which coverage may be provided
 12 under a health plan, a determination of whether or
 13 not such items and services are covered or reimburs-
 14 able under the coverage and terms of the contract.

15 “(3) ENROLLEE.—The term enrollee means a
 16 participant or beneficiary.

17 “(4) GRIEVANCE.—The term ‘grievance’ means
 18 any enrollee complaint that does not involve a cov-
 19 erage determination.

20 “(5) PRIOR AUTHORIZATION DETERMINA-

21 TION.—The term ‘prior authorization determination’
 22 means a coverage determination prior to the provi-
 23 sion of the items and services as a condition of cov-
 24 erage of the items and services under the coverage.

1 “(6) TREATING HEALTH CARE PROFES-
 2 SIONAL.—The term ‘treating health care profes-
 3 sional’ with respect to a group health plan, health
 4 insurance issuer or provider sponsored organization
 5 means a practitioner who is acting within the scope
 6 of their State licensure or certification for the deliv-
 7 ery of health care services and who is primarily re-
 8 sponsible for delivering those services to the enrollee.

9 “(7) UTILIZATION REVIEW.—The term ‘utiliza-
 10 tion review’ with respect to a group health plan or
 11 health insurance coverage means a set of formal
 12 techniques designed to monitor the use of, or evalu-
 13 ate the clinical necessity, appropriateness, efficacy,
 14 or efficiency of, health care services, procedures, or
 15 settings. Techniques may include ambulatory review,
 16 prospective review, second opinion, certification, con-
 17 current review, case management, discharge plan-
 18 ning or retrospective review.”.

19 (b) ENFORCEMENT.—Section 502(c)(1) of the Em-
 20 ployee Retirement Income Security Act of 1974 (29
 21 U.S.C. 1132(c)(1)) is amended by inserting after “or sec-
 22 tion 101(e)(1)” the following: “, or fails to comply with
 23 a coverage determination as required under section
 24 503(e)(6),”.

1 (c) CONFORMING AMENDMENT.—The table of con-
 2 tents in section 1 of the Employee Retirement Income Se-
 3 curity Act of 1974 is amended by striking the item relat-
 4 ing to section 503 and inserting the following new item:

“Sec. 503. Claims procedures, coverage determination, grievances and appeals.”.

5 **TITLE II—INDIVIDUAL RIGHTS**
 6 **WITH RESPECT TO PERSONAL**
 7 **MEDICAL INFORMATION**

8 **SEC. 201. SHORT TITLE.**

9 This title may be cited as the “Personal Medical In-
 10 formation Access Act”.

11 **Subtitle A—Access to Medical**
 12 **Records**

13 **SEC. 211. INSPECTION AND COPYING OF PROTECTED**
 14 **HEALTH INFORMATION.**

15 (a) IN GENERAL.—At the request of an individual
 16 and except as provided in subsection (b), a health care
 17 provider, health plan, employer, health or life insurer,
 18 school, or university shall permit an individual who is the
 19 subject of protected health information or the individual’s
 20 designee, to inspect and copy protected health information
 21 concerning the individual, including records created under
 22 section 212 that such entity maintains. Such entity may
 23 set forth appropriate procedures to be followed for such
 24 inspection or copying and may require an individual to pay

1 reasonable costs associated with such inspection or copy-
2 ing.

3 (b) EXCEPTIONS.—Unless ordered by a court of com-
4 petent jurisdiction, an entity described in subsection (a)
5 is not required to permit the inspection or copying of pro-
6 tected health information if any of the following conditions
7 are met:

8 (1) ENDANGERMENT TO LIFE OR SAFETY.—
9 The entity determines that the disclosure of the in-
10 formation could reasonably be expected to endanger
11 the life or physical safety of an individual.

12 (2) CONFIDENTIAL SOURCE.—The information
13 identifies, or could reasonably lead to the identifica-
14 tion of, a person who provided information under a
15 promise of confidentiality concerning the individual
16 who is the subject of the information.

17 (3) INFORMATION COMPILED IN ANTICIPATION
18 OF LITIGATION.—The information is compiled prin-
19 cipally—

20 (A) in the reasonable anticipation of a
21 civil, criminal, or administrative action or pro-
22 ceeding; or

23 (B) for use in such an action or proceed-
24 ing.

1 (4) RESEARCH PURPOSES.—The information
2 was collected for a research project monitored by an
3 institutional review board, such project is not com-
4 plete, and the researcher involved reasonably believes
5 that access to such information would harm the con-
6 duct of the research or invalidate or undermine the
7 validity of the research.

8 (c) DENIAL OF A REQUEST FOR INSPECTION OR
9 COPYING.—If an entity described in subsection (a) denies
10 a request for inspection or copying pursuant to subsection
11 (b), the entity shall inform the individual in writing of—

12 (1) the reasons for the denial of the request for
13 inspection or copying;

14 (2) any procedures for further review of the de-
15 nial; and

16 (3) the individual's right to file with the entity
17 a concise statement setting forth the request for in-
18 spection or copying.

19 (d) STATEMENT REGARDING REQUEST.—If an indi-
20 vidual has filed a statement under subsection (c)(3), the
21 entity in any subsequent disclosure of the portion of the
22 information requested under subsection (a) shall include—

23 (1) a copy of the individual's statement; and

24 (2) a concise statement of the reasons for deny-
25 ing the request for inspection or copying.

1 (e) INSPECTION AND COPYING OF SEGREGABLE POR-
 2 TION.—An entity described in subsection (a) shall permit
 3 the inspection and copying under subsection (a) of any
 4 reasonably segregable portion of protected health informa-
 5 tion after deletion of any portion that is exempt under
 6 subsection (b).

7 (f) DEADLINE.—An entity described in subsection (a)
 8 shall comply with or deny, in accordance with subsection
 9 (c), a request for inspection or copying of protected health
 10 information under this section not later than 45 days after
 11 the date on which the entity receives the request.

12 (g) RULES GOVERNING AGENTS.—An agent of an en-
 13 tity described in subsection (a) shall not be required to
 14 provide for the inspection and copying of protected health
 15 information, except where—

16 (1) the protected health information is retained
 17 by the agent; and

18 (2) the agent has received in writing a request
 19 from the entity involved to fulfill the requirements of
 20 this section;

21 at which time such information shall be provided to the
 22 requesting entity. Such requesting entity shall comply with
 23 subsection (f) with respect to any such information.

24 (h) RULE OF CONSTRUCTION.—This section shall not
 25 be construed to require an entity described in subsection

1 (a) to conduct a formal, informal, or other hearing or pro-
 2 ceeding concerning a request for inspection or copying of
 3 protected health information.

4 **SEC. 212. AMENDMENT OF PROTECTED HEALTH INFORMA-**
 5 **TION.**

6 (a) REQUIREMENT.—

7 (1) IN GENERAL.—Except as provided in sub-
 8 section (b) and subject to paragraph (2), a health
 9 care provider, health plan, employer, health or life
 10 insurer, school, or university that receives from an
 11 individual a request in writing to amend protected
 12 health information shall—

13 (A) amend such information as requested;

14 (B) inform the individual of the amend-
 15 ment that has been made; and

16 (C) make reasonable efforts to inform any
 17 person to whom the unamended portion of the
 18 information was previously disclosed, of any
 19 nontechnical amendment that has been made.

20 (2) COMPLIANCE.—An entity described in para-
 21 graph (1) shall comply with the requirements of
 22 such paragraph within 45 days of the date on which
 23 the request involved is received if the entity—

24 (A) created the protected health informa-
 25 tion involved; and

1 (B) determines that such information is in
2 fact inaccurate.

3 (b) REFUSAL TO AMEND.—If an entity described in
4 subsection (a) refuses to make the amendment requested
5 under such subsection, the entity shall inform the individ-
6 ual in writing of—

7 (1) the reasons for the refusal to make the
8 amendment;

9 (2) any procedures for further review of the re-
10 fusal; and

11 (3) the individual's right to file with the entity
12 a concise statement setting forth the requested
13 amendment and the individual's reasons for dis-
14 agreeing with the refusal.

15 (c) STATEMENT OF DISAGREEMENT.—If an individ-
16 ual has filed a statement of disagreement under subsection
17 (b)(3), the entity involved, in any subsequent disclosure
18 of the disputed portion of the information—

19 (1) shall include a copy of the individual's
20 statement; and

21 (2) may include a concise statement of the rea-
22 sons for not making the requested amendment.

23 (d) RULES GOVERNING AGENTS.—The agent of an
24 entity described in subsection (a) shall not be required to

1 make amendments to protected health information, except
2 where—

3 (1) the protected health information is retained
4 by the agent; and

5 (2) the agent has been asked by such entity to
6 fulfill the requirements of this section.

7 If the agent is required to comply with this section as pro-
8 vided for in paragraph (2), such agent shall be subject
9 to the 45-day deadline described in subsection (a).

10 (e) REPEATED REQUESTS FOR AMENDMENTS.—If an
11 entity described in subsection (a) receives a request for
12 an amendment of information as provided for in such sub-
13 section and a statement of disagreement has been filed
14 pursuant to subsection (c), the entity shall inform the indi-
15 vidual of such filing and shall not be required to carry
16 out the procedures required under this section.

17 (f) RULES OF CONSTRUCTION.—This section shall
18 not be construed to—

19 (1) require that an entity described in sub-
20 section (a) conduct a formal, informal, or other
21 hearing or proceeding concerning a request for an
22 amendment to protected health information;

23 (2) require a provider to amend an individual's
24 protected health information as to the type, dura-

1 tion, or quality of treatment the individual believes
 2 he or she should have been provided; or

3 (3) permit any deletions or alterations of the
 4 original information.

5 **SEC. 213. NOTICE OF CONFIDENTIALITY PRACTICES.**

6 (a) PREPARATION OF WRITTEN NOTICE.—A health
 7 care provider, health plan, health oversight agency, public
 8 health authority, employer, health or life insurer, health
 9 researcher, school or university shall post or provide, in
 10 writing and in a clear and conspicuous manner, notice of
 11 the entity’s confidentiality practices, that shall include—

12 (1) a description of an individual’s rights with
 13 respect to protected health information;

14 (2) the procedures established by the entity for
 15 the exercise of the individual’s rights; and

16 (3) the right to obtain a copy of the notice of
 17 the confidentiality practices required under this sub-
 18 title.

19 (b) MODEL NOTICE.—The Secretary, in consultation
 20 with the National Committee on Vital and Health Statis-
 21 tics and the National Association of Insurance Commis-
 22 sioners, and after notice and opportunity for public com-
 23 ment, shall develop and disseminate model notices of con-
 24 fidentiality practices. Use of the model notice shall serve

1 as an absolute defense against claims of receiving inappro-
 2 priate notice.

3 **Subtitle B—Establishment of** 4 **Safeguards**

5 **SEC. 221. ESTABLISHMENT OF SAFEGUARDS.**

6 A health care provider, health plan, health oversight
 7 agency, public health authority, employer, health or life
 8 insurer, health researcher, law enforcement official, school
 9 or university shall establish and maintain appropriate ad-
 10 ministrative, technical, and physical safeguards to protect
 11 the confidentiality, security, accuracy, and integrity of
 12 protected health information created, received, obtained,
 13 maintained, used, transmitted, or disposed of by such en-
 14 tity.

15 **Subtitle C—Enforcement;** 16 **Definitions**

17 **SEC. 231. CIVIL PENALTY.**

18 (a) VIOLATION.—A health care provider, health re-
 19 searcher, health plan, health oversight agency, public
 20 health agency, law enforcement agency, employer, health
 21 or life insurer, school, or university, or the agent of any
 22 such individual or entity, who the Secretary, in consulta-
 23 tion with the Attorney General, determines has substan-
 24 tially and materially failed to comply with this Act shall,
 25 for a violation of this title, be subject, in addition to any

1 other penalties that may be prescribed by law, to a civil
 2 penalty of not more than \$500 for each such violation,
 3 but not to exceed \$5,000 in the aggregate for multiple vio-
 4 lations.

5 (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—
 6 Section 1128A of the Social Security Act, other than sub-
 7 sections (a) and (b) and the second sentence of subsection
 8 (f) of that section, shall apply to the imposition of a civil,
 9 monetary, or exclusionary penalty under this section in the
 10 same manner as such provisions apply with respect to the
 11 imposition of a penalty under section 1128A of such Act.

12 **SEC. 232. DEFINITIONS.**

13 In this title:

14 (1) AGENT.—The term “agent” means a person
 15 who represents and acts for another under the con-
 16 tract or relation of agency, or whose function is to
 17 bring about, modify, affect, accept performance of,
 18 or terminate contractual obligations between the
 19 principal and a third person, including a contractor.

20 (2) DISCLOSE.—The term “disclose” means to
 21 release, transfer, provide access to, or otherwise di-
 22 vulge protected health information to any person
 23 other than the individual who is the subject of such
 24 information. Such term includes the initial disclosure

1 and any subsequent redisclosures of protected health
2 information.

3 (3) EMPLOYER.—The term “employer” has the
4 meaning given such term under section 3(5) of the
5 Employee Retirement Income Security Act of 1974
6 (29 U.S.C. 1002(5)), except that such term shall in-
7 clude only employers of 2 or more employees.

8 (4) HEALTH CARE PROVIDER.—The term
9 “health care provider” means a person who, with re-
10 spect to a specific item of protected health informa-
11 tion, receives, creates, uses, maintains, or discloses
12 the information while acting in whole or in part in
13 the capacity of—

14 (A) a person who is licensed, certified, reg-
15 istered, or otherwise authorized by Federal or
16 State law to provide an item or service that
17 constitutes health care in the ordinary course of
18 business, or practice of a profession;

19 (B) a Federal, State, or employer-spon-
20 sored program that directly provides items or
21 services that constitute health care to bene-
22 ficiaries; or

23 (C) an officer, employee, or agent of a per-
24 son described in subparagraph (A) or (B).

1 (5) HEALTH OR LIFE INSURER.—The term
2 “health or life insurer” means a health insurance
3 issuer as defined in section 2791 of the Public
4 Health Service Act (42 U.S.C. 300gg–91) or a life
5 insurance company as defined in section 816 of the
6 Internal Revenue Code of 1986.

7 (6) HEALTH PLAN.—The term “health plan”
8 means any health insurance plan, including any hos-
9 pital or medical service plan, dental or other health
10 service plan or health maintenance organization
11 plan, provider sponsored organization, or other pro-
12 gram providing or arranging for the provision of
13 health benefits, whether or not funded through the
14 purchase of insurance.

15 (7) PERSON.—The term “person” means a gov-
16 ernment, governmental subdivision, agency or au-
17 thority; corporation; company; association; firm;
18 partnership; society; estate; trust; joint venture; indi-
19 vidual; individual representative; tribal government;
20 and any other legal entity.

21 (8) PROTECTED HEALTH INFORMATION.—The
22 term “protected health information” means any in-
23 formation (including demographic information)
24 whether or not recorded in any form or medium—

1 (A) that relates to the past, present or fu-
2 ture—

3 (i) physical or mental health or condi-
4 tion of an individual (including the condi-
5 tion or other attributes of individual cells
6 or their components);

7 (ii) provision of health care to an indi-
8 vidual; or

9 (iii) payment for the provision of
10 health care to an individual;

11 (B) that is created by a health care pro-
12 vider, health plan, health researcher, health
13 oversight agency, public health authority, em-
14 ployer, law enforcement official, health or life
15 insurer, school or university; and

16 (C) that is not nonidentifiable health infor-
17 mation.

18 (9) SCHOOL OR UNIVERSITY.—The term
19 “school or university” means an institution or place
20 for instruction or education, including an elementary
21 school, secondary school, or institution of higher
22 learning, a college, or an assemblage of colleges
23 united under one corporate organization or govern-
24 ment.

1 (10) SECRETARY.—The term “Secretary”
2 means the Secretary of Health and Human Services.

3 (11) WRITING.—The term “writing” means
4 writing in either a paper-based or computer-based
5 form, including electronic signatures.

6 **TITLE III—GENETIC** 7 **INFORMATION AND SERVICES**

8 **SEC. 301. SHORT TITLE.**

9 This title may be cited as the “Genetic Information
10 Nondiscrimination in Health Insurance Act of 1998”.

11 **SEC. 302. AMENDMENTS TO EMPLOYEE RETIREMENT IN-** 12 **COME SECURITY ACT OF 1974.**

13 (a) PROHIBITION OF HEALTH DISCRIMINATION ON
14 THE BASIS OF GENETIC INFORMATION OR GENETIC
15 SERVICES.—

16 (1) NO ENROLLMENT RESTRICTION FOR GE-
17 NETIC SERVICES.—Section 702(a)(1)(F) of the Em-
18 ployee Retirement Income Security Act of 1974 (29
19 U.S.C. 1182(a)(1)(F)) is amended by inserting be-
20 fore the period the following: “(including informa-
21 tion about a request for or receipt of genetic serv-
22 ices)”.

23 (2) NO DISCRIMINATION IN GROUP PREMIUMS
24 BASED ON PREDICTIVE GENETIC INFORMATION.—
25 Subpart B of part 7 of subtitle B of title I of the

1 Employee Retirement Income Security Act of 1974
 2 (29 U.S.C. 1185 et seq.) (as amended by section
 3 111) is further amended by adding at the end the
 4 following:

5 **“SEC. 714. PROHIBITING PREMIUM DISCRIMINATION**
 6 **AGAINST GROUPS ON THE BASIS OF PRE-**
 7 **DICTIVE GENETIC INFORMATION.**

8 “A group health plan, or a health insurance issuer
 9 offering group health insurance coverage in connection
 10 with a group health plan, shall not adjust premium or con-
 11 tribution amounts for a group on the basis of predictive
 12 genetic information concerning an individual in the group
 13 or a family member of the individual (including informa-
 14 tion about a request for or receipt of genetic services).”.

15 (3) CONFORMING AMENDMENT.—Section
 16 702(b) of the Employee Retirement Income Security
 17 Act of 1974 (29 U.S.C. 1182(b)) is amended by
 18 adding at the end the following:

19 “(3) REFERENCE TO RELATED PROVISION.—
 20 For a provision prohibiting the adjustment of pre-
 21 mium or contribution amounts for a group under a
 22 group health plan on the basis of predictive genetic
 23 information (including information about a request
 24 for or receipt of genetic services), see section 714.”.

1 (b) LIMITATION ON COLLECTION OF PREDICTIVE
2 GENETIC INFORMATION.—Section 702 of the Employee
3 Retirement Income Security Act of 1974 (29 U.S.C. 1182)
4 is amended by adding at the end the following:

5 “(c) COLLECTION OF PREDICTIVE GENETIC INFOR-
6 MATION.—

7 “(1) LIMITATION ON REQUESTING OR REQUIR-
8 ING PREDICTIVE GENETIC INFORMATION.—Except
9 as provided in paragraph (2), a group health plan,
10 or a health insurance issuer offering health insur-
11 ance coverage in connection with a group health
12 plan, shall not request or require predictive genetic
13 information concerning an individual or a family
14 member of the individual (including information
15 about a request for or receipt of genetic services).

16 “(2) INFORMATION NEEDED FOR DIAGNOSIS,
17 TREATMENT, OR PAYMENT.—

18 “(A) IN GENERAL.—Notwithstanding para-
19 graph (1), a group health plan or health insur-
20 ance issuer that provides health care items and
21 services to an individual or dependent may re-
22 quest (but may not require) that such individ-
23 ual or dependent disclose, or authorize the col-
24 lection or disclosure of, predictive genetic infor-
25 mation for purposes of diagnosis, treatment, or

1 payment relating to the provision of health care
 2 items and services to such individual or depend-
 3 ent.

4 “(B) NOTICE OF CONFIDENTIALITY PRAC-
 5 TICES AND DESCRIPTION OF SAFEGUARDS.—As
 6 a part of a request under subparagraph (A),
 7 the group health plan or health insurance issuer
 8 shall provide to the individual or dependent a
 9 description of the procedures in place to safe-
 10 guard the confidentiality, as described in sec-
 11 tions 213 and 221 of the Patients’ Bill of
 12 Rights Act, of such individually identifiable in-
 13 formation.”.

14 (c) DEFINITIONS.—Section 733(d) of the Employee
 15 Retirement Income Security Act of 1974 (29 U.S.C.
 16 1191b(d)) is amended by adding at the end the following:

17 “(5) FAMILY MEMBER.—The term ‘family
 18 member’ means with respect to an individual—

19 “(A) the spouse of the individual;

20 “(B) a dependent child of the individual,
 21 including a child who is born to or placed for
 22 adoption with the individual; and

23 “(C) all other individuals related by blood
 24 to the individual or the spouse or child de-
 25 scribed in subparagraph (A) or (B).

1 “(6) GENETIC INFORMATION.—The term ‘ge-
 2 netic information’ means information about genes,
 3 gene products, or inherited characteristics that may
 4 derive from an individual or a family member (in-
 5 cluding information about a request for or receipt of
 6 genetic services).

7 “(7) GENETIC SERVICES.—The term ‘genetic
 8 services’ means health services provided to obtain,
 9 assess, or interpret genetic information for diag-
 10 nostic and therapeutic purposes, and for genetic
 11 education and counseling.

12 “(8) PREDICTIVE GENETIC INFORMATION.—

13 “(A) IN GENERAL.—The term ‘predictive
 14 genetic information’ means—

15 “(i) information about an individual’s
 16 genetic tests which are associated with a
 17 statistically significant increased risk of
 18 developing a disease or disorder;

19 “(ii) information about genetic tests
 20 of family members of the individual; or

21 “(iii) information about the occur-
 22 rence of a disease or disorder in family
 23 members that predicts a statistically sig-
 24 nificant increased risk of a disease or dis-
 25 order in the individual.

1 “(B) EXCEPTIONS.—The term ‘predictive
2 genetic information’ shall not include—

3 “(i) information about the sex or age
4 of the individual;

5 “(ii) information derived from routine
6 physical tests, such as the chemical, blood,
7 or urine analyses of the individual, unless
8 such analyses are genetic tests; and

9 “(iii) information about physical
10 exams of the individual and other informa-
11 tion relevant to determining the current
12 health status of the individual so long as
13 such information does not include informa-
14 tion described in clauses (i), (ii), or (iii) of
15 subparagraph (A).

16 “(9) GENETIC TEST.—The term ‘genetic test’
17 means the analysis of human DNA, RNA, chro-
18 mosomes, proteins, and certain metabolites, in order
19 to detect disease-related genotypes, mutations,
20 phenotypes, or karyotypes.”.

21 (d) EFFECTIVE DATE.—Except as provided in this
22 section, this section and the amendments made by this
23 section shall apply with respect to group health plans for
24 plan years beginning 1 year after the date of the enact-
25 ment of this Act.

1 **SEC. 303. AMENDMENTS TO THE PUBLIC HEALTH SERVICE**
 2 **ACT.**

3 (a) AMENDMENTS RELATING TO THE GROUP MAR-
 4 KET.—

5 (1) PROHIBITION OF HEALTH DISCRIMINATION
 6 ON THE BASIS OF GENETIC INFORMATION IN THE
 7 GROUP MARKET.—

8 (A) IN GENERAL.—Subpart 2 of part A of
 9 title XXVII of the Public Health Service Act
 10 (42 U.S.C. 300gg–4 et seq.) is amended by
 11 adding at the end the following:

12 **“SEC. 2706. PROHIBITING PREMIUM DISCRIMINATION**
 13 **AGAINST GROUPS ON THE BASIS OF PRE-**
 14 **DICTIVE GENETIC INFORMATION IN THE**
 15 **GROUP MARKET.**

16 “A group health plan, or a health insurance issuer
 17 offering group health insurance coverage in connection
 18 with a group health plan shall not adjust premium or con-
 19 tribution amounts for a group on the basis of predictive
 20 genetic information concerning an individual in the group
 21 or a family member of the individual (including informa-
 22 tion about a request for or receipt of genetic services).”.

23 (B) CONFORMING AMENDMENT.—Section
 24 2702(b) of the Public Health Service Act (42
 25 U.S.C. 300gg–1(b)) is amended by adding at
 26 the end the following:

1 “(3) REFERENCE TO RELATED PROVISION.—
 2 For a provision prohibiting the adjustment of pre-
 3 mium or contribution amounts for a group under a
 4 group health plan on the basis of predictive genetic
 5 information (including information about a request
 6 for or receipt of genetic services), see section 2706.”.

7 (C) LIMITATION ON COLLECTION AND DIS-
 8 CLOSURE OF PREDICTIVE GENETIC INFORMA-
 9 TION.—Section 2702 of the Public Health Serv-
 10 ice Act (42 U.S.C. 300gg-1) is amended by
 11 adding at the end the following:

12 “(c) COLLECTION OF PREDICTIVE GENETIC INFOR-
 13 MATION.—

14 “(1) LIMITATION ON REQUESTING OR REQUIR-
 15 ING PREDICTIVE GENETIC INFORMATION.—Except
 16 as provided in paragraph (2), a group health plan,
 17 or a health insurance issuer offering health insur-
 18 ance coverage in connection with a group health
 19 plan, shall not request or require predictive genetic
 20 information concerning an individual or a family
 21 member of the individual (including information
 22 about a request for or receipt of genetic services).

23 “(2) INFORMATION NEEDED FOR DIAGNOSIS,
 24 TREATMENT, OR PAYMENT.—

1 “(A) IN GENERAL.—Notwithstanding para-
2 graph (1), a group health plan or health insur-
3 ance issuer that provides health care items and
4 services to an individual or dependent may re-
5 quest (but may not require) that such individ-
6 ual or dependent disclose, or authorize the col-
7 lection or disclosure of, predictive genetic infor-
8 mation for purposes of diagnosis, treatment, or
9 payment relating to the provision of health care
10 items and services to such individual or depend-
11 ent.

12 “(B) NOTICE OF CONFIDENTIALITY PRAC-
13 TICES AND DESCRIPTION OF SAFEGUARDS.—As
14 a part of a request under subparagraph (A),
15 the group health plan or health insurance issuer
16 shall provide to the individual or dependent a
17 description of the procedures in place to safe-
18 guard the confidentiality, as described in sec-
19 tions 213 and 221 of the Patients’ Bill of
20 Rights Act, of such individually identifiable in-
21 formation.”.

22 (2) DEFINITIONS.—Section 2791(d) of the Pub-
23 lic Health Service Act (42 U.S.C. 300gg–91(d)) is
24 amended by adding at the end the following:

1 “(15) FAMILY MEMBER.—The term ‘family
2 member’ means, with respect to an individual—

3 “(A) the spouse of the individual;

4 “(B) a dependent child of the individual,
5 including a child who is born to or placed for
6 adoption with the individual; and

7 “(C) all other individuals related by blood
8 to the individual or the spouse or child de-
9 scribed in subparagraph (A) or (B).

10 “(16) GENETIC INFORMATION.—The term ‘ge-
11 netic information’ means information about genes,
12 gene products, or inherited characteristics that may
13 derive from an individual or a family member.

14 “(17) GENETIC SERVICES.—The term ‘genetic
15 services’ means health services provided to obtain,
16 assess, or interpret genetic information for diag-
17 nostic and therapeutic purposes, and for genetic
18 education and counseling.

19 “(18) PREDICTIVE GENETIC INFORMATION.—

20 “(A) IN GENERAL.—The term ‘predictive
21 genetic information’ means—

22 “(i) information about an individual’s
23 genetic tests which is associated with a
24 statistically significant increased risk of
25 developing a disease or disorder;

1 “(ii) information about genetic tests
2 of family members of the individual; or

3 “(iii) information about the occur-
4 rence of a disease or disorder in family
5 members that predicts a statistically sig-
6 nificant increased risk of a disease or dis-
7 order in the individual.

8 “(B) EXCEPTIONS.—The term ‘predictive
9 genetic information’ shall not include—

10 “(i) information about the sex or age
11 of the individual;

12 “(ii) information derived from routine
13 physical tests, such as the chemical, blood,
14 or urine analyses of the individual, unless
15 such analyses are genetic tests; and

16 “(iii) information about physical
17 exams of the individual and other informa-
18 tion relevant to determining the current
19 health status of the individual so long as
20 such information does not include informa-
21 tion described in clauses (i), (ii), or (iii) of
22 subparagraph (A).

23 “(19) GENETIC TEST.—The term ‘genetic test’
24 means the analysis of human DNA, RNA, chro-
25 mosomes, proteins, and certain metabolites, in order

1 to detect disease-related genotypes, mutations,
 2 phenotypes, or karyotypes.”.

3 (b) AMENDMENT RELATING TO THE INDIVIDUAL
 4 MARKET.—The first subpart 3 of part B of title XXVII
 5 of the Public Health Service Act (42 U.S.C. 300gg–11 et
 6 seq.) (relating to other requirements) is amended—

7 (1) by redesignating such subpart as subpart
 8 II; and

9 (2) by adding at the end the following:

10 **“SEC. 2752. PROHIBITION OF HEALTH DISCRIMINATION ON**
 11 **THE BASIS OF PREDICTIVE GENETIC INFOR-**
 12 **MATION.**

13 “(a) PROHIBITION ON PREDICTIVE GENETIC INFOR-
 14 MATION AS A CONDITION OF ELIGIBILITY.—A health in-
 15 surance issuer offering health insurance coverage in the
 16 individual market may not use predictive genetic informa-
 17 tion as a condition of eligibility of an individual to enroll
 18 in individual health insurance coverage (including infor-
 19 mation about a request for or receipt of genetic services).

20 “(b) PROHIBITION ON PREDICTIVE GENETIC INFOR-
 21 MATION IN SETTING PREMIUM RATES.—A health insur-
 22 ance issuer offering health insurance coverage in the indi-
 23 vidual market shall not adjust premium rates for individ-
 24 uals on the basis of predictive genetic information concern-
 25 ing such an enrollee or a family member of the enrollee

1 (including information about a request for or receipt of
2 genetic services).

3 “(c) COLLECTION OF PREDICTIVE GENETIC INFOR-
4 MATION.—

5 “(1) LIMITATION ON REQUESTING OR REQUIR-
6 ING PREDICTIVE GENETIC INFORMATION.—Except
7 as provided in paragraph (2), a health insurance
8 issuer offering health insurance coverage in the indi-
9 vidual market shall not request or require predictive
10 genetic information concerning an individual or a
11 family member of the individual (including informa-
12 tion about a request for or receipt of genetic serv-
13 ices).

14 “(2) INFORMATION NEEDED FOR DIAGNOSIS,
15 TREATMENT, OR PAYMENT.—

16 “(A) IN GENERAL.—Notwithstanding para-
17 graph (1), a health insurance issuer that pro-
18 vides health care items and services to an indi-
19 vidual or dependent may request (but may not
20 require) that such individual or dependent dis-
21 close, or authorize the collection or disclosure
22 of, predictive genetic information for purposes
23 of diagnosis, treatment, or payment relating to
24 the provision of health care items and services
25 to such individual or dependent.

1 “(B) NOTICE OF CONFIDENTIALITY PRAC-
 2 TICES AND DESCRIPTION OF SAFEGUARDS.—As
 3 a part of a request under subparagraph (A),
 4 the health insurance issuer shall provide to the
 5 individual or dependent a description of the
 6 procedures in place to safeguard the confiden-
 7 tiality, as described in sections 213 and 221 of
 8 the Patients’ Bill of Rights Act, of such individ-
 9 ually identifiable information.”.

10 (c) EFFECTIVE DATE.—The amendments made by
 11 this section shall apply with respect to—

12 (1) group health plans, and health insurance
 13 coverage offered in connection with group health
 14 plans, for plan years beginning after 1 year after the
 15 date of enactment of this Act; and

16 (2) health insurance coverage offered, sold,
 17 issued, renewed, in effect, or operated in the individ-
 18 ual market after 1 year after the date of enactment
 19 of this Act.

20 **SEC. 304. AMENDMENTS TO THE INTERNAL REVENUE CODE**
 21 **OF 1986.**

22 (a) PROHIBITION OF HEALTH DISCRIMINATION ON
 23 THE BASIS OF PREDICTIVE GENETIC INFORMATION.—

1 (1) IN GENERAL.—Subchapter B of chapter
2 100 of the Internal Revenue Code of 1986 is amend-
3 ed by adding at the end the following:

4 **“SEC. 9813. PROHIBITING HEALTH DISCRIMINATION**
5 **AGAINST GROUPS ON THE BASIS OF PRE-**
6 **DICTIVE GENETIC INFORMATION.**

7 “A group health plan, or a health insurance issuer
8 offering group health insurance coverage in connection
9 with a group health plan, shall not adjust premium or con-
10 tribution amounts for a group on the basis of predictive
11 genetic information concerning an individual in the group
12 or a family member of the individual (including informa-
13 tion about a request for or receipt of genetic services).”.

14 (2) CONFORMING AMENDMENT.—Section
15 9802(b) of the Internal Revenue Code of 1986 is
16 amended by adding at the end the following:

17 “(3) REFERENCE TO RELATED PROVISION.—
18 For a provision prohibiting the adjustment of pre-
19 mium or contribution amounts for a group under a
20 group health plan on the basis of predictive genetic
21 information (including information about a request
22 for or the receipt of genetic services), see section
23 9813.”.

24 (3) AMENDMENT TO TABLE OF SECTIONS.—
25 The table of sections for subchapter B of chapter

1 100 of the Internal Revenue Code of 1986 is amend-
 2 ed by adding at the end the following:

“Sec. 9813. Prohibiting premium discrimination against groups on the basis of
 predictive genetic information.”.

3 (b) LIMITATION ON COLLECTION OF PREDICTIVE
 4 GENETIC INFORMATION.—Section 9802 of the Internal
 5 Revenue Code of 1986 is amended by adding at the end
 6 the following:

7 “(c) COLLECTION OF PREDICTIVE GENETIC INFOR-
 8 MATION.—

9 “(1) LIMITATION ON REQUESTING OR REQUIR-
 10 ING PREDICTIVE GENETIC INFORMATION.—Except
 11 as provided in paragraph (2), a group health plan,
 12 or a health insurance issuer offering health insur-
 13 ance coverage in connection with a group health
 14 plan, shall not request or require predictive genetic
 15 information concerning an individual or a family
 16 member of the individual (including information
 17 about a request for or receipt of genetic services).

18 “(2) INFORMATION NEEDED FOR DIAGNOSIS,
 19 TREATMENT, OR PAYMENT.—

20 “(A) IN GENERAL.—Notwithstanding para-
 21 graph (1), a group health plan or health insur-
 22 ance issuer that provides health care items and
 23 services to an individual or dependent may re-
 24 quest (but may not require) that such individ-

1 ual or dependent disclose, or authorize the col-
 2 lection or disclosure of, predictive genetic infor-
 3 mation for purposes of diagnosis, treatment, or
 4 payment relating to the provision of health care
 5 items and services to such individual or depend-
 6 ent.

7 “(B) NOTICE OF CONFIDENTIALITY PRAC-
 8 TICES; DESCRIPTION OF SAFEGUARDS.—As a
 9 part of a request under subparagraph (A), the
 10 group health plan or health insurance issuer
 11 shall provide to the individual or dependent a
 12 description of the procedures in place to safe-
 13 guard the confidentiality, as described in sec-
 14 tions 213 and 221 of the Patients’ Bill of
 15 Rights Act, of such individually identifiable in-
 16 formation.”.

17 (c) DEFINITIONS.—Section 9832(d) of the Internal
 18 Revenue Code of 1986 is amended by adding at the end
 19 the following:

20 “(6) FAMILY MEMBER.—The term ‘family
 21 member’ means, with respect to an individual—

22 “(A) the spouse of the individual;

23 “(B) a dependent child of the individual,
 24 including a child who is born to or placed for
 25 adoption with the individual; and

1 “(C) all other individuals related by blood
2 to the individual or the spouse or child de-
3 scribed in subparagraph (A) or (B).

4 “(7) GENETIC INFORMATION.—The term ‘ge-
5 netic information’ means information about genes,
6 gene products, or inherited characteristics that may
7 derive from an individual or a family member.

8 “(8) GENETIC SERVICES.—The term ‘genetic
9 services’ means health services provided to obtain,
10 assess, or interpret genetic information for diag-
11 nostic and therapeutic purposes, and for genetic
12 education and counseling.

13 “(9) PREDICTIVE GENETIC INFORMATION.—

14 “(A) IN GENERAL.—The term ‘predictive
15 genetic information’ means—

16 “(i) information about an individual’s
17 genetic tests which is associated with a
18 statistically significant increased risk of
19 developing a disease or disorder;

20 “(ii) information about genetic tests
21 of family members of the individual; or

22 “(iii) information about the occur-
23 rence of a disease or disorder in family
24 members that predicts a statistically sig-

1 nificant increased risk of a disease or dis-
2 order in the individual.

3 “(B) EXCEPTIONS.—The term ‘predictive
4 genetic information’ shall not include—

5 “(i) information about the sex or age
6 of the individual;

7 “(ii) information derived from routine
8 physical tests, such as the chemical, blood,
9 or urine analyses of the individual, unless
10 such analyses are genetic tests; and

11 “(iii) information about physical
12 exams of the individual and other informa-
13 tion relevant to determining the current
14 health status of the individual so long as
15 such information does not include informa-
16 tion described in clauses (i), (ii), or (iii) of
17 subparagraph (A).

18 “(10) GENETIC TEST.—The term ‘genetic test’
19 means the analysis of human DNA, RNA, chro-
20 mosomes, proteins, and certain metabolites, in order
21 to detect disease-related genotypes, mutations,
22 phenotypes, or karyotypes.”.

23 (d) EFFECTIVE DATE.—Except as provided in this
24 section, this section and the amendments made by this
25 section shall apply with respect to group health plans for

1 plan years beginning after 1 year after the date of the
2 enactment of this Act.

3 **TITLE IV—HEALTHCARE** 4 **QUALITY RESEARCH**

5 **SEC. 401. SHORT TITLE.**

6 This title may be cited as the “Healthcare Quality
7 Research Act of 1998”.

8 **SEC. 402. AMENDMENT TO THE PUBLIC HEALTH SERVICE** 9 **ACT.**

10 Title IX of the Public Health Service Act (42 U.S.C.
11 299 et seq.) is amended to read as follows:

12 **“TITLE IX—AGENCY FOR** 13 **HEALTHCARE QUALITY RE-** 14 **SEARCH**

15 **“PART A—ESTABLISHMENT AND GENERAL** 16 **DUTIES**

17 **“SEC. 901. MISSION AND DUTIES.**

18 “(a) IN GENERAL.—There is established within the
19 Public Health Service an agency to be known as the Agen-
20 cy for Healthcare Quality Research. In carrying out this
21 subsection, the Secretary shall redesignate the Agency for
22 Health Care Policy and Research as the Agency for
23 Healthcare Quality Research.

24 “(b) MISSION.—The purpose of the Agency is to en-
25 hance the quality, appropriateness, and effectiveness of

1 healthcare services, and access to such services, through
 2 the establishment of a broad base of scientific research
 3 and through the promotion of improvements in clinical
 4 practice, including the prevention of diseases and other
 5 health conditions. The Agency shall promote healthcare
 6 quality improvement by—

7 “(1) conducting and supporting research that
 8 develops and presents scientific evidence regarding
 9 all aspects of healthcare, including—

10 “(A) the development and assessment of
 11 methods for the purposes of enhancing patient
 12 participation in their own care and for facilitat-
 13 ing shared patient-physician decision-making;

14 “(B) the outcomes, effectiveness, and cost-
 15 effectiveness of healthcare practices, including
 16 preventive measures and primary care;

17 “(C) existing and innovative technologies;

18 “(D) the costs and utilization of, and ac-
 19 cess to healthcare;

20 “(E) the ways in which healthcare services
 21 are organized, delivered, and financed and the
 22 interaction and impact of these factors on the
 23 quality of patient care;

24 “(F) methods for measuring quality and
 25 strategies for improving quality; and

1 “(G) ways in which patients, consumers,
 2 and practitioners acquire new information
 3 about best practices and health benefits, and
 4 the determinants of their use of this informa-
 5 tion;

6 “(2) synthesizing and disseminating available
 7 scientific evidence for use by patients, consumers,
 8 practitioners, providers, purchasers, policy makers,
 9 and educators; and

10 “(3) advancing private and public efforts to im-
 11 prove healthcare quality.

12 “(c) REQUIREMENTS WITH RESPECT TO RURAL
 13 AREAS AND PRIORITY POPULATIONS.—In carrying out
 14 subsection (b), the Director shall undertake and support
 15 research, demonstration projects, and evaluations with re-
 16 spect to—

17 “(1) the delivery of health services in rural
 18 areas (including frontier areas);

19 “(2) health services for low-income groups, and
 20 minority groups;

21 “(3) the health of children;

22 “(4) the elderly; and

23 “(5) people with special healthcare needs, in-
 24 cluding chronic care and end-of-life healthcare.

1 “(d) APPOINTMENT OF DIRECTOR.—There shall be
 2 at the head of the Agency an official to be known as the
 3 Director for Healthcare Quality Research. The Director
 4 shall be appointed by the Secretary. The Secretary, acting
 5 through the Director, shall carry out the authorities and
 6 duties established in this title.

7 **“SEC. 902. GENERAL AUTHORITIES.**

8 “(a) IN GENERAL.—In carrying out section 901(b),
 9 the Director shall support demonstration projects, conduct
 10 and support research, evaluations, training, research net-
 11 works, multi-disciplinary centers, technical assistance, and
 12 the dissemination of information, on healthcare, and on
 13 systems for the delivery of such care, including activities
 14 with respect to—

15 “(1) the quality, effectiveness, efficiency, appro-
 16 priateness and value of healthcare services;

17 “(2) quality measurement and improvement;

18 “(3) the outcomes, cost, cost-effectiveness, and
 19 use of healthcare services and access to such serv-
 20 ices;

21 “(4) clinical practice, including primary care
 22 and practice-oriented research;

23 “(5) healthcare technologies, facilities, and
 24 equipment;

1 “(6) healthcare costs, productivity, and market
2 forces;

3 “(7) health promotion and disease prevention,
4 including clinical preventive services;

5 “(8) health statistics, surveys, database devel-
6 opment, and epidemiology; and

7 “(9) medical liability.

8 “(b) HEALTH SERVICES TRAINING GRANTS.—The
9 Director may provide training grants in the field of health
10 services research related to activities authorized under
11 subsection (a), to include pre- and post-doctoral fellow-
12 ships and training programs, young investigator awards,
13 and other programs and activities as appropriate. In car-
14 rying out this subsection, the Director shall make use of
15 funds made available under section 478.

16 “(c) MULTIDISCIPLINARY CENTERS.—The Director
17 may provide financial assistance to assist in meeting the
18 costs of planning and establishing new centers, and oper-
19 ating existing and new centers, for multidisciplinary
20 health services research, demonstration projects, evalua-
21 tions, training, and policy analysis with respect to the mat-
22 ters referred to in subsection (a).

23 “(d) RELATION TO CERTAIN AUTHORITIES REGARD-
24 ING SOCIAL SECURITY.—Activities authorized in this sec-
25 tion may include, and shall be appropriately coordinated

1 with experiments, demonstration projects, and other relat-
 2 ed activities authorized by the Social Security Act and the
 3 Social Security Amendments of 1967. Activities under
 4 subsection (a)(2) of this section that affect the programs
 5 under titles XVIII and XIX of the Social Security Act
 6 shall be carried out consistent with section 1142 of such
 7 Act.

8 “(e) DISCLAIMER.—Nothing in this title shall be con-
 9 strued to imply that the Agency’s role is to mandate na-
 10 tional standards of clinical practice or quality healthcare
 11 standards. Recommendations resulting from projects
 12 funded and published by the Agency shall include a cor-
 13 responding disclaimer.

14 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
 15 tion shall be construed to imply that quality measurement
 16 is a science of uniform national standards. In research and
 17 quality improvement activities, the Agency shall consider
 18 a wide range of choices, providers, healthcare delivery sys-
 19 tems, and individual preferences.

20 **“PART B—HEALTHCARE IMPROVEMENT**

21 **RESEARCH**

22 **“SEC. 911. HEALTHCARE OUTCOME IMPROVEMENT RE-** 23 **SEARCH.**

24 “(a) EVIDENCE RATING SYSTEMS.—In collaboration
 25 with experts from the public and private sector, the Agen-

1 cy shall identify and disseminate methods or systems used
 2 to assess healthcare research results, particularly to rate
 3 the strength of the scientific evidence behind healthcare
 4 practice and technology recommendations in the research
 5 literature. The Agency shall make methods or systems for
 6 evidence rating widely available. Agency publications con-
 7 taining healthcare recommendations shall indicate the
 8 level of substantiating evidence using such methods or sys-
 9 tems.

10 “(b) HEALTHCARE IMPROVEMENT RESEARCH CEN-
 11 TERS AND PROVIDER-BASED RESEARCH NETWORKS.—

12 “(1) IN GENERAL.—In order to address the full
 13 continuum of care and outcomes research, to link re-
 14 search to practice improvement, and to speed the
 15 dissemination of research findings to community
 16 practice settings, the Agency shall employ research
 17 strategies and mechanisms that will link research di-
 18 rectly with clinical practice in geographically diverse
 19 locations throughout the United States, including—

20 “(A) Healthcare Improvement Research
 21 Centers that combine demonstrated multidisci-
 22 plinary expertise in outcomes or quality im-
 23 provement research with linkages to relevant
 24 sites of care;

1 “(B) Practice-based Research Networks,
 2 including plan, facility, or delivery system sites
 3 of care (especially primary care), that can
 4 evaluate and promote quality improvement; and
 5 “(C) other innovative mechanisms or strat-
 6 egies.

7 “(2) REQUIREMENTS.—The Director is author-
 8 ized to establish the requirements for entities apply-
 9 ing for grants under this subsection.

10 “(c) EXPANSION OF THE HEALTH SERVICES RE-
 11 SEARCH WORKFORCE.—

12 “(1) GRANTS.—The Agency shall, through the
 13 awarding of grants, support eligible entities at geo-
 14 graphically diverse locations throughout the United
 15 States to enable such entities to carry out research
 16 training programs that are dedicated to health serv-
 17 ices research training at the doctoral, post-doctoral,
 18 and junior faculty levels.

19 “(2) REQUIREMENTS.—In developing priorities
 20 for the allocation of training funds under this sub-
 21 section, the Director shall take into consideration
 22 shortages in the number of trained researchers ad-
 23 dressing the priority populations.

1 **“SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE**
2 **ORGANIZATION AND DELIVERY.**

3 “(a) SUPPORT FOR EFFORTS TO DEVELOP INFOR-
4 MATION ON QUALITY.—

5 “(1) SCIENTIFIC AND TECHNICAL SUPPORT.—

6 In its role as the principal agency for healthcare
7 quality research, the Agency shall provide scientific
8 and technical support for private and public efforts
9 to improve healthcare quality, including accrediting
10 organizations.

11 “(2) ROLE OF THE AGENCY.—With respect to
12 paragraph (1), the role of the Agency shall include—

13 “(A) the identification and assessment of
14 methods for the evaluation of the health of en-
15 rollees in health plans by type of plan, provider,
16 and provider arrangements;

17 “(B) the ongoing development, testing, and
18 dissemination of quality measures, including
19 measures of health and functional outcomes,
20 that take into account appropriate variations in
21 individual preferences;

22 “(C) the compilation and dissemination of
23 healthcare quality measures developed in the
24 private and public sector;

25 “(D) assistance in the development of im-
26 proved healthcare information systems;

1 “(E) the development of survey tools for
 2 the purpose of measuring participant and bene-
 3 ficiary assessments of their healthcare; and

4 “(F) the integration of information on
 5 quality into purchaser and consumer decision-
 6 making processes.

7 “(b) DEMONSTRATION PROGRAM REGARDING CEN-
 8 TERS FOR EDUCATION AND RESEARCH ON THERA-
 9 PEUTICS.—

10 “(1) IN GENERAL.—The Secretary, acting
 11 through the Director and in consultation with the
 12 Commissioner of Food and Drugs, shall establish a
 13 demonstration program for the purpose of making
 14 one or more grants for the establishment and oper-
 15 ation of one or more centers to carry out the activi-
 16 ties specified in paragraph (2).

17 “(2) REQUIRED ACTIVITIES.—The activities re-
 18 ferred to in this paragraph are the following:

19 “(A) The conduct of state-of-the-art clini-
 20 cal research for the following purposes:

21 “(i) To increase awareness of—

22 “(I) new uses of drugs, biological
 23 products, and devices;

1 “(II) ways to improve the effective use of drugs, biological products,
2
3 and devices; and

4 “(III) risks of new uses and risks
5 of combinations of drugs and biological
6 products.

7 “(ii) To provide objective clinical information to the following individuals and
8
9 entities:

10 “(I) Healthcare practitioners and
11 other providers of Healthcare goods or
12 services.

13 “(II) Pharmacy benefit managers
14 and purchasers.

15 “(III) Health maintenance organizations and other managed
16
17 healthcare organizations.

18 “(IV) Healthcare insurers and
19 governmental agencies.

20 “(V) Patients and consumers.

21 “(iii) To improve the quality of
22 healthcare while reducing the cost of
23 Healthcare through—

24 “(I) the appropriate use of drugs,
25 biological products, or devices; and

1 “(II) the prevention of adverse
2 effects of drugs, biological products,
3 and devices and the consequences of
4 such effects, such as unnecessary hos-
5 pitalizations.

6 “(B) The conduct of research on the com-
7 parative effectiveness, cost-effectiveness, and
8 safety of drugs, biological products, and devices.

9 “(C) Such other activities as the Secretary
10 determines to be appropriate, except that a
11 grant may not be expended to assist the Sec-
12 retary in the review of new drugs.

13 “(3) APPLICATION FOR GRANT.—A grant under
14 paragraph (1) may be made only if an application
15 for the grant is submitted to the Secretary and the
16 application is in such form, is made in such manner,
17 and contains such agreements, assurances, and in-
18 formation as the Secretary determines to be nec-
19 essary to carry out this section.

20 “(4) PEER REVIEW.—A grant under paragraph
21 (1) may be made only if the application for the
22 grant has undergone appropriate technical and sci-
23 entific peer review.

1 “(c) REDUCING ERRORS IN MEDICINE.—The Direc-
2 tor shall conduct and support research and build private-
3 public partnerships to—

4 “(1) identify the causes of preventable
5 healthcare errors and patient injury in healthcare
6 delivery systems;

7 “(2) develop, demonstrate, and evaluate strate-
8 gies for reducing errors and improving patient safe-
9 ty; and

10 “(3) promote the implementation of effective
11 strategies throughout the healthcare industry.

12 **“SEC. 913. INFORMATION ON QUALITY AND COST OF CARE.**

13 “(a) IN GENERAL.—In carrying out 902(a), the Di-
14 rector shall—

15 “(1) collect data from a nationally representa-
16 tive sample of the population on the cost and use of
17 healthcare, including the types of healthcare services
18 Americans use, their access to healthcare services,
19 frequency of use, how much is paid for the services
20 used, the source of those payments, the types and
21 costs of private health insurance, access, satisfac-
22 tion, and quality of care for the general population
23 and also for children, uninsured persons, poor and
24 near-poor individuals, and persons with special
25 healthcare needs, including end-of-life healthcare;

1 “(2) develop databases and tools that enable
2 States to track the quality, access, and use of
3 healthcare services provided to their residents; and

4 “(3) enter into agreements with public or pri-
5 vate entities to use, link, or acquire databases for re-
6 search authorized under this title.

7 “(b) QUALITY AND OUTCOMES INFORMATION.—

8 “(1) IN GENERAL.—To enhance the under-
9 standing of the quality of care, the determinants of
10 health outcomes and functional status, the needs of
11 special populations as well as an understanding of
12 these changes over time, their relationship to
13 healthcare access and use, and to monitor the overall
14 national impact of Federal and State policy changes
15 on healthcare, the Director, beginning in fiscal year
16 2000, shall ensure that the survey conducted under
17 subsection (a)(1) will—

18 “(A) provide information on the quality of
19 care and patient outcomes for frequently occur-
20 ring clinical conditions for a nationally rep-
21 resentative sample of the population; and

22 “(B) provide reliable national estimates for
23 children and persons with special healthcare
24 needs through the use of supplements or peri-
25 odic expansions of the survey.

1 “(2) ANNUAL REPORT.—Beginning in fiscal
2 year 2002, the Secretary, acting through the Direc-
3 tor, shall submit to Congress an annual report on
4 national trends in the quality of healthcare provided
5 to the American people.

6 **“SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IM-**
7 **PROVEMENT.**

8 “‘In order to foster a range of innovative approaches
9 to the management and communication of health informa-
10 tion, the Agency shall support research to evaluate and
11 initiatives to advance—

12 “(1) the use of information systems for the
13 study of healthcare quality, including the generation
14 of both individual provider and plan-level compara-
15 tive performance measures;

16 “(2) training for healthcare practitioners and
17 researchers in the use of information systems;

18 “(3) the creation of effective linkages between
19 various sources of health information, including the
20 development of information networks;

21 “(4) the delivery and coordination of evidence-
22 based healthcare services, using real-time decision-
23 support programs;

1 “(5) the structure, content, definition, and cod-
 2 ing of health information data and medical vocabu-
 3 laries and shall consult with other Federal entities;

4 “(6) the evaluation and use of computer-based
 5 health records in outpatient and inpatient settings
 6 as a personal health record for individual health as-
 7 sessment and maintenance, and for monitoring pub-
 8 lic health and outcomes of care within populations;
 9 and

10 “(7) the protection of individually identifiable
 11 information in health services research and
 12 healthcare quality improvement.

13 **“SEC. 915. RESEARCH SUPPORTING PRIMARY CARE DELIV-**
 14 **ERY AND ACCESS IN UNDERSERVED AREAS.**

15 “(a) PREVENTIVE SERVICES TASK FORCE.—

16 “(1) PURPOSE.—The Agency shall provide on-
 17 going administrative, research, and technical support
 18 for the operation of the Preventive Services Task
 19 Force. The Agency shall coordinate and support the
 20 dissemination of the Preventive Services Task Force
 21 recommendations.

22 “(2) OPERATION.—The Preventive Services
 23 Task Force shall review the scientific evidence relat-
 24 ed to the effectiveness, appropriateness, and cost-ef-
 25 fectiveness of clinical preventive services for the pur-

pose of developing recommendations, and updating previous recommendations, regarding their usefulness in daily clinical practice. In carrying out its responsibilities under paragraph (1), the Task Force shall not be subject to the provisions of Appendix 2 of title 5, United States Code.

“(b) PRIMARY CARE DELIVERY RESEARCH.—

“(1) IN GENERAL.—There is established within the Agency a Center for Primary Care Delivery Research (referred to in this subsection as the ‘Center’) that shall serve as the principal source of funding for primary care delivery research in the Department of Health and Human Services. For purposes of this paragraph, primary care delivery research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

“(2) RESEARCH.—In carrying out this section, the Center shall conduct and support research on—

“(A) the nature and characteristics of primary care delivery practice;

“(B) producing evidence for the management of commonly occurring clinical problems;

1 “(C) the management of undifferentiated
2 clinical problems;

3 “(D) the continuity and coordination of
4 health services; and

5 “(E) the application and impact of tele-
6 medicine and other distance technologies.

7 “(3) DEMONSTRATION.—The Agency shall sup-
8 port demonstrations into the use of new information
9 tools aimed at improving shared decision-making be-
10 tween patients and their care-givers.

11 **“SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVA-**
12 **TION.**

13 “(a) IN GENERAL.—The Director shall promote inno-
14 vation in evidence-based clinical practice and healthcare
15 technologies by—

16 “(1) conducting and supporting research on the
17 development, diffusion, and use of healthcare tech-
18 nology;

19 “(2) developing, evaluating, and disseminating
20 methodologies for healthcare practice and technology
21 assessment;

22 “(3) conducting intramural and supporting ex-
23 tramural assessments of existing and new healthcare
24 practices and technologies;

1 “(4) promoting education, training, and provid-
 2 ing technical assistance in the use of healthcare
 3 practice and healthcare technology assessment meth-
 4 odologies and results; and

5 “(5) working with the National Library of Med-
 6 icine and the public and private sector to develop an
 7 electronic clearinghouse of currently available assess-
 8 ments and those in progress.

9 “(b) SPECIFICATION OF PROCESS.—

10 “(1) IN GENERAL.—Not later than June 1,
 11 1999, the Director shall develop and publish a de-
 12 scription of the methods used by the Agency and its
 13 contractors for practice and technology assessment.

14 “(2) CONSULTATIONS.—In carrying out this
 15 subsection, the Director shall cooperate and consult
 16 with the Administrator of the Health Care Financ-
 17 ing Administration, the Director of the National In-
 18 stitutes of Health, the Commissioner of Food and
 19 Drugs, and the heads of any other interested Fed-
 20 eral department or agency, professional societies,
 21 and other private and public entities.

22 “(3) METHODOLOGY.—The methods employed
 23 in practice and technology assessments under para-
 24 graph (1) shall consider—

25 “(A) safety, efficacy, and effectiveness;

1 “(B) legal, social, and ethical implications;

2 “(C) costs, benefits, and cost-effectiveness;

3 “(D) comparisons to alternative tech-
4 nologies and practices; and

5 “(E) requirements of Food and Drug Ad-
6 ministration approval to avoid duplication.

7 “(c) SPECIFIC ASSESSMENTS.—

8 “(1) IN GENERAL.—The Director shall conduct
9 and support specific assessments of healthcare tech-
10 nologies and practices.

11 “(2) GRANTS AND CONTRACTS.—The Director
12 may make grants to, or enter into cooperative agree-
13 ments or contracts with, entities described in para-
14 graph (3) for the establishment of collaborative ar-
15 rangements for the purpose of conducting assess-
16 ments of experimental, emerging, existing, or poten-
17 tially outmoded healthcare technologies, and for re-
18 lated activities.

19 “(3) ELIGIBLE ENTITIES.—An entity described
20 in this paragraph is an entity that is determined to
21 be appropriate by the Director, including academic
22 medical centers, research institutions, professional
23 organizations, third party payers, other govern-
24 mental agencies, and consortia of appropriate re-

1 search entities established for the purpose of con-
2 ducting technology assessments.

3 **“SEC. 917. COORDINATION OF FEDERAL GOVERNMENT**
4 **QUALITY IMPROVEMENT EFFORTS.**

5 “(a) REQUIREMENT.—

6 “(1) IN GENERAL.—The Secretary, acting
7 through the Director, shall coordinate all research,
8 evaluations, and demonstrations related to health
9 services research and quality measurement and im-
10 provement activities undertaken and supported by
11 the Federal Government.

12 “(2) SPECIFIC ACTIVITIES.—The Director, in
13 collaboration with the appropriate Federal officials
14 representing all concerned executive agencies and de-
15 partments, shall develop and manage a process to—

16 “(A) improve interagency coordination, pri-
17 ority setting, and the use and sharing of re-
18 search findings and data pertaining to Federal
19 quality improvement programs and health serv-
20 ices research;

21 “(B) strengthen the research information
22 infrastructure, including databases, pertaining
23 to Federal health services research and
24 healthcare quality improvement initiatives;

1 “(C) set specific goals for participating
 2 agencies and departments to further health
 3 services research and healthcare quality im-
 4 provement; and

5 “(D) strengthen the management of Fed-
 6 eral healthcare quality improvement programs.

7 “(b) STUDY BY THE INSTITUTE OF MEDICINE.—

8 “(1) IN GENERAL.—To provide the Department
 9 of Health and Human Services with independent, ex-
 10 pert advice in redesigning its quality oversight func-
 11 tions, and pertinent research programs, the Sec-
 12 retary shall enter into a contract with the Institute
 13 of Medicine—

14 “(A) to describe and evaluate current qual-
 15 ity improvement research and monitoring proc-
 16 esses through—

17 “(i) an overview of pertinent health
 18 services research activities and quality im-
 19 provement efforts with particular attention
 20 paid to those performed by the peer review
 21 organizations;

22 “(ii) an analysis of the various part-
 23 nership activities that the Department of
 24 Health and Human Services has pursued

1 with private sector accreditation and other
 2 quality measurement organizations;

3 “(iii) the exploration of programmatic
 4 areas where partnership activities could be
 5 pursued to improve quality oversight of the
 6 medicare and medicaid programs under ti-
 7 tles XVIII and XIX of the Social Security
 8 Act; and

9 “(iv) an identification of opportunities
 10 for enhancing health system efficiency
 11 through simplification and reduction in re-
 12 dundancy of public and private sector qual-
 13 ity improvement efforts; and

14 “(B) to identify options and make rec-
 15 ommendations to improve the efficiency and ef-
 16 fectiveness of such quality improvement pro-
 17 grams and to optimize public/private sector ac-
 18 creditation bodies through—

19 “(i) the improved coordination of ac-
 20 tivities across the medicare and medicaid
 21 programs under titles XVIII and XIX of
 22 the Social Security Act and various health
 23 services research programs;

24 “(ii) greater consistency and stand-
 25 ardization of oversight activities across tra-

ditional fee-for-service and managed care components of these programs;

“(iii) the strengthening of patient choice and participation by incorporating state-of-the-art quality monitoring tools and making information on quality available; and

“(iv) the enhancement of the most effective programs, consolidation as appropriate, and elimination of duplicative activities within various federal agencies.

“(2) REQUIREMENTS.—

“(A) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the preparation—

“(i) not later than 12 months after the date of enactment of this title, of a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the medicare, medicaid, and CHIP programs under titles XVIII, XIX, and XXI of the Social Security Act; and

“(ii) not later than 24 months after the date of enactment of this title, of a

1 final report containing recommendations
 2 for a comprehensive system and public-pri-
 3 vate partnerships for healthcare quality
 4 improvement.

5 “(B) REPORTS.—The Secretary shall sub-
 6 mit the reports described in subparagraph (A)
 7 to the Committee on Finance and the Commit-
 8 tee on Labor and Human Resources of the Sen-
 9 ate and the Committee on Ways and Means and
 10 the Committee on Commerce of the House of
 11 Representatives.

12 **“PART C—FOUNDATION FOR HEALTHCARE**
 13 **QUALITY RESEARCH**

14 **“SEC. 921. FOUNDATION FOR HEALTHCARE QUALITY RE-**
 15 **SEARCH.**

16 “(a) IN GENERAL.—The Secretary shall, acting
 17 through the Director of the Agency for Healthcare Quality
 18 Research, establish a nonprofit corporation to be known
 19 as the Foundation for Healthcare Research (hereafter in
 20 this section referred to as the ‘Foundation’). The Founda-
 21 tion shall not be an agency or instrumentality of the
 22 United States Government.

23 “(b) PURPOSE OF FOUNDATION.—The purpose of
 24 the Foundation shall be to—

1 “(1) support the Agency for Healthcare Quality
2 Research in its mission;

3 “(2) foster public-private partnerships to sup-
4 port the programs and activities of the Agency;

5 “(3) advance collaboration with healthcare re-
6 searchers from universities, industry, and nonprofit
7 organizations; and

8 “(4) develop linkages with users of healthcare
9 and quality research, including patients, consumers,
10 practitioners and other healthcare providers, health
11 plans and insurers, large private or public sector
12 purchasers of healthcare, healthcare policy makers,
13 and healthcare educators.

14 “(c) CERTAIN ACTIVITIES OF FOUNDATION.—In car-
15 rying out subsection (b), the Foundation may solicit and
16 accept gifts, grants, and other donations, establish ac-
17 counts, and invest and expend funds in support of a broad
18 range of research, training, dissemination, and other ac-
19 tivities with respect to the purpose described in such sub-
20 section. In addition, the Foundation is authorized to sup-
21 port the following:

22 “(1) A program to provide and administer en-
23 dowed positions that are associated with the re-
24 search program of the Agency for Healthcare Qual-
25 ity Research. Such endowments may be expended for

1 the compensation of individuals holding the posi-
2 tions, for staff, equipment, quarters, travel, and
3 other expenditures that are appropriate in support-
4 ing the endowed positions.

5 “(2) A program to provide and administer fel-
6 lowships and grants to research personnel in order
7 to work and study in association with the Agency for
8 Healthcare Quality Research. Such fellowships and
9 grants may include stipends, travel, health insurance
10 benefits, and other appropriate expenses. The recipi-
11 ents of fellowships shall be selected by the donors
12 and the Foundation upon the recommendation of the
13 Agency for Healthcare Quality Research, and shall
14 be subject to the agreement of the Director of the
15 Agency for Healthcare Quality Research and the Ex-
16 ecutive Director of the Foundation.

17 “(d) GENERAL STRUCTURE OF FOUNDATION; NON-
18 PROFIT STATUS.—

19 “(1) BOARD OF DIRECTORS.—The Foundation
20 shall have a Board of Directors (in this section re-
21 ferred to as the Board), which shall be established
22 and conducted in accordance with subsection (e).
23 The Board shall establish the general policies of the
24 Foundation for carrying out subsection (b), includ-

1 ing the establishment of the bylaws of the Founda-
2 tion.

3 “(2) EXECUTIVE DIRECTOR.—The Foundation
4 shall have an executive director (in this section re-
5 ferred to as the ‘Director’), who shall be appointed
6 by the Board, who shall serve at the pleasure of the
7 Board, and for whom the Board shall establish the
8 rate of compensation. Subject to compliance with the
9 policies and bylaws established by the Board pursu-
10 ant to paragraph (1), the Director shall be respon-
11 sible for the daily operations of the Foundation in
12 carrying out subsection (b).

13 “(3) NONPROFIT STATUS.—In carrying out
14 subsection (b), the Board shall establish such poli-
15 cies and bylaws under paragraph (1), and the Direc-
16 tor shall carry out such activities under paragraph
17 (2), as may be necessary to ensure that the Founda-
18 tion maintains status as an organization that—

19 “(A) is described in subsection (c)(3) of
20 section 501 of the Internal Revenue Code of
21 1986; and

22 “(B) is, under subsection (a) of such sec-
23 tion, exempt from taxation.

24 “(e) BOARD OF DIRECTORS.—

25 “(1) CERTAIN BYLAWS.—

1 “(A) IN GENERAL.—The Board shall en-
2 sure that bylaws established under subsection
3 (a)(1) include bylaws for the following:

4 “(i) Policies for the selection of the
5 officers, employees, agents, and contractors
6 of the Foundation.

7 “(ii) Policies, including ethical stand-
8 ards, for the acceptance and disposition of
9 donations to the Foundation and for the
10 disposition of the assets of the Foundation.

11 “(iii) Policies for the conduct of the
12 general operations of the Foundation.

13 “(iv) Policies for writing, editing,
14 printing, and publishing of books and other
15 materials, and the acquisition of patents
16 and licenses for devices and procedures de-
17 veloped by the Foundation.

18 “(B) REQUIREMENTS.—The Board shall
19 ensure that the bylaws established under sub-
20 section (d)(1) (and activities carried out under
21 such bylaws) do not—

22 “(i) reflect unfavorably upon the abil-
23 ity of the Foundation, or the Agency for
24 Healthcare Quality Research, to carry out

1 its responsibilities or official duties in a
2 fair and objective manner; or

3 “(ii) compromise, or appear to com-
4 promise, the integrity of any governmental
5 program or any officer or employee in-
6 volved in such program.

7 “(2) COMPOSITION.—

8 “(A) IN GENERAL.—Subject to subpara-
9 graph (B), the Board shall be composed of 7 in-
10 dividuals, appointed in accordance with para-
11 graph (4), who collectively possess education or
12 experience appropriate for representing the con-
13 stituencies described in subsection (b). Each
14 such individual shall be a voting member of the
15 Board.

16 “(B) ADDITIONAL MEMBERS.—The Board
17 may, through amendments to the bylaws of the
18 Foundation, provide that the number of mem-
19 bers of the Board shall be a greater number
20 than the number specified in subparagraph (A).

21 “(3) CHAIR.—The Board shall, from among the
22 members of the Board, designate an individual to
23 serve as the chair of the Board (in this subsection
24 referred to as the ‘Chair’).

1 “(4) APPOINTMENTS, VACANCIES, AND
2 TERMS.—The following shall apply to the Board:

3 “(A) Any vacancy in the membership of
4 the Board shall be filled by appointment by the
5 Board, after consideration of suggestions made
6 by the Chair and the Director regarding the ap-
7 pointments. Any such vacancy shall be filled not
8 later than the expiration of the 180-day period
9 beginning on the date on which the vacancy oc-
10 curs.

11 “(B) The term of office of each member of
12 the Board appointed under subparagraph (A)
13 shall be 5 years. A member of the Board may
14 continue to serve after the expiration of the
15 term of the member until the expiration of the
16 180-day period beginning on the date on which
17 the term of the member expires.

18 “(C) A vacancy in the membership of the
19 Board shall not affect the power of the Board
20 to carry out the duties of the Board. If a mem-
21 ber of the Board does not serve the full term
22 applicable under subparagraph (B), the individ-
23 ual appointed to fill the resulting vacancy shall
24 be appointed for the remainder of the term of
25 the predecessor of the individual.

1 “(5) COMPENSATION.—Members of the Board
2 may not receive compensation for service on the
3 Board. The members may be reimbursed for travel,
4 subsistence, and other necessary expenses incurred
5 in carrying out the duties of the Board.

6 “(f) CERTAIN RESPONSIBILITIES OF EXECUTIVE DI-
7 RECTOR.—In carrying out subsection (d)(2), the Director
8 shall carry out the following functions:

9 “(1) Hire, promote, compensate, and discharge
10 officers and employees of the Foundation, and define
11 the duties of the officers and employees.

12 “(2) Accept and administer donations to the
13 Foundation, and administer the assets of the Foun-
14 dation.

15 “(3) Establish a process for the selection of
16 candidates for holding endowed positions under sub-
17 section (c).

18 “(4) Enter into such financial agreements as
19 are appropriate in carrying out the activities of the
20 Foundation.

21 “(5) Take such action as may be necessary to
22 acquire patents and licenses for devices and proce-
23 dures developed by the Foundation and the employ-
24 ees of the Foundation.

1 “(6) Adopt, alter, and use a corporate seal,
2 which shall be judicially noticed.

3 “(7) Commence and respond to judicial pro-
4 ceedings in the name of the Foundation.

5 “(8) Other functions that are appropriate in the
6 determination of the Director.

7 “(g) GENERAL PROVISIONS.—

8 “(1) AUTHORITY FOR ACCEPTING FUNDS.—The
9 Director of the Agency for Healthcare Quality Re-
10 search may accept and utilize, on behalf of the Fed-
11 eral Government, any gift, donation, bequest, or de-
12 vise of real or personal property from the Founda-
13 tion for the purpose of aiding or facilitating the
14 work of such Agency. Funds may be accepted and
15 utilized by such Director under the preceding sen-
16 tence without regard to whether the funds are des-
17 ignated as general-purpose funds or special-purpose
18 funds. Any funds transferred under this paragraph
19 shall be subject to all Federal limitations relating to
20 federally funded research.

21 “(2) AUTHORITY FOR ACCEPTANCE OF VOL-
22 UNTARY SERVICES.—

23 “(A) IN GENERAL.—The Director of the
24 Agency for Healthcare Quality Research may
25 accept, on behalf of the Federal Government,

1 any voluntary services provided to such Agency
2 by the Foundation for the purpose of aiding or
3 facilitating the work of such Agency. In the
4 case of an individual, such Director may accept
5 the services provided under the preceding sen-
6 tence by the individual for not more than 2
7 years.

8 “(B) LIMITATION.—The limitation estab-
9 lished in subparagraph (A) regarding the period
10 of time in which services may be accepted ap-
11 plies to each individual who is not an employee
12 of the Federal Government and who serves in
13 association with the Agency for Healthcare
14 Quality Research pursuant to financial support
15 from the Foundation.

16 “(3) ADMINISTRATIVE CONTROL.—No officer,
17 employee, or member of the Board of the Founda-
18 tion may exercise any administrative or managerial
19 control over any Federal employee.

20 “(4) APPLICABILITY OF CERTAIN STANDARDS
21 TO NON-FEDERAL EMPLOYEES.—In the case of any
22 individual who is not an employee of the Federal
23 Government and who serves in association with the
24 Agency for Healthcare Quality Research pursuant to
25 financial support from the Foundation, the Founda-

tion shall negotiate a memorandum of understanding with the individual and the Director of the Agency for Healthcare Quality Research specifying that the individual—

“(A) shall be subject to the ethical and procedural standards regulating Federal employment, scientific investigation, and research findings (including publications and patents) that are required of individuals employed by the Agency for Healthcare Quality Research, including standards under this Act, the Ethics in Government Act, and the Technology Transfer Act; and

“(B) shall be subject to such ethical and procedural standards under chapter 11 of title 18, United States Code (relating to conflicts of interest), as the Director of such Agency determines is appropriate, except such memorandum may not provide that the individual shall be subject to the standards of section 209 of such chapter.

“(5) FINANCIAL CONFLICTS OF INTEREST.—

Any individual who is an officer, employee, or member of the Board of the Foundation may not directly or indirectly participate in the consideration or de-

1 termination by the Foundation of any question af-
 2 fecting—

3 “(A) any direct or indirect financial inter-
 4 est of the individual; or

5 “(B) any direct or indirect financial inter-
 6 est of any business organization or other entity
 7 of which the individual is an officer or employee
 8 or in which the individual has a direct or indi-
 9 rect financial interest.

10 “(6) AUDITS; AVAILABILITY OF RECORDS.—The
 11 Foundation shall—

12 “(A) provide for biennial audits of the fi-
 13 nancial condition of the Foundation; and

14 “(B) make such audits, and all other
 15 records, documents, and other papers of the
 16 Foundation, available to the Secretary and the
 17 Comptroller General of the United States for
 18 examination or audit.

19 “(7) REPORTS.—

20 “(A) IN GENERAL.—Not later than Feb-
 21 ruary 1 of each fiscal year, the Foundation
 22 shall publish a report describing the activities of
 23 the Foundation during the preceding fiscal
 24 year. Each such report shall include for the fis-
 25 cal year involved a comprehensive statement of

1 the operations, activities, financial condition,
2 and accomplishments of the Foundation.

3 “(B) FINANCIAL REQUIREMENT.—With re-
4 spect to the financial condition of the Founda-
5 tion, each report under subparagraph (A) shall
6 include the source, and a description of, all gifts
7 to the Foundation of real or personal property,
8 and the source and amount of all gifts to the
9 Foundation of money. Each such report shall
10 include a specification of any restrictions on the
11 purposes for which gifts to the Foundation may
12 be used.

13 “(C) PUBLIC INSPECTION.—The Founda-
14 tion shall make copies of each report submitted
15 under subparagraph (A) available for public in-
16 spection, and shall upon request provide a copy
17 of the report to any individual for a charge not
18 exceeding the cost of providing the copy.

19 “(8) LIAISON FROM THE AGENCY FOR
20 HEALTHCARE QUALITY RESEARCH.—The Director of
21 the Agency for Healthcare Quality Research shall
22 serve as the liaison representative of such Agency
23 and the Foundation.

24 “(h) FEDERAL FUNDING.—

25 “(1) AUTHORITY FOR FINANCIAL SUPPORT.—

1 “(A) IN GENERAL.—The Secretary, acting
2 through the Director of the Agency for
3 Healthcare Quality Research, shall—

4 “(i) for fiscal year 1999, support the
5 work of the Committee, established pursu-
6 ant to subsection (i); and

7 “(ii) for fiscal year 2000 and each
8 subsequent fiscal year, make a grant to the
9 Foundation.

10 “(B) LIMITATIONS.—Financial support
11 under subparagraph (A) may be expended—

12 “(i) in the case of the Committee,
13 only for the purpose of carrying out the
14 duties established in subsection (i); and

15 “(ii) in the case of the Foundation,
16 only for the purpose of the administrative
17 expenses of the Foundation.

18 “(C) REMAINING FUNDS.—For the pur-
19 poses described in subparagraph (B), any por-
20 tion of the financial support provided to the
21 Committee under subparagraph (A)(i) for fiscal
22 year 1999 that remains unobligated after the
23 Committee completes the duties established in
24 subsection (i) shall be available to the Founda-
25 tion.

1 “(2) FUNDS.—

2 “(A) AUTHORIZATION OF APPROPRIA-
3 TIONS.—For the purpose of providing financial
4 support under paragraph (1), there is author-
5 ized to be appropriated for the Foundation
6 \$500,000 for each fiscal year.

7 “(B) GRANTS.—For the purpose of grants
8 under paragraph (1), the Secretary may for
9 each fiscal year make available not more than
10 \$500,000 from the amounts appropriated for
11 the fiscal year for the programs of the Depart-
12 ment of Health and Human Services. Such
13 amounts may be made available without regard
14 to whether amounts have been appropriated
15 under subparagraph (A).

16 “(3) CERTAIN RESTRICTION.—If the Founda-
17 tion receives Federal funds for the purpose of serv-
18 ing as a fiscal intermediary between Federal agen-
19 cies, the Foundation may not receive such funds for
20 the indirect costs of carrying out such purpose in an
21 amount exceeding 10 percent of the direct costs of
22 carrying out such purpose. The preceding sentence
23 may not be construed as authorizing the expenditure
24 of any grant under paragraph (1) for such purpose.

25 “(i) ESTABLISHMENT OF COMMITTEE.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish in accordance with this subsection a committee
3 (referred to in this subsection as the ‘Committee’)
4 to carry out the functions described in paragraph
5 (2).

6 “(2) FUNCTIONS.—The functions referred to in
7 paragraph (1) for the Committee are as follows:

8 “(A) To carry out such activities as may
9 be necessary to incorporate the Foundation
10 under the laws of the State involved, including
11 serving as incorporators for the Foundation.
12 Such activities shall include ensuring that the
13 articles of incorporation for the Foundation re-
14 quire that the Foundation be established and
15 operated in accordance with the applicable pro-
16 visions of this part (or any successor to this
17 part), including such provisions as may be in
18 effect pursuant to amendments enacted after
19 the date of the enactment of the Healthcare
20 Quality Research Act of 1998.

21 “(B) To ensure that the Foundation quali-
22 fies for and maintains the status described in
23 subsection (d)(3) (regarding taxation).

24 “(C) To establish the general policies and
25 initial bylaws of the Foundation, which bylaws

1 shall include the bylaws described in subsections
 2 (d)(3) and (e)(1).

3 “(D) To provide for the initial operation of
 4 the Foundation, including providing for quar-
 5 ters, equipment, and staff.

6 “(E) To appoint the initial members of the
 7 Board in accordance with the requirements es-
 8 tablished in subsection (e)(2)(A) for the com-
 9 position of the Board and establish their respec-
 10 tive terms, and other such qualifications as the
 11 Committee may determine to be appropriate.

12 “(3) COMPLETION OF FUNCTIONS OF COMMIT-
 13 TEE; INITIAL MEETING OF BOARD.—

14 “(A) IN GENERAL.—The Committee shall
 15 complete the functions required in paragraph
 16 (1) not later than 1 year following the appoint-
 17 ment of the last member of the Committee. The
 18 Committee shall terminate upon the expiration
 19 of the 30-day period beginning on the date on
 20 which the Secretary determines that the func-
 21 tions have been completed.

22 “(B) INITIAL MEETING.—The initial meet-
 23 ing of the Board shall be held not later than 90
 24 days after the Committee has completed its
 25 functions.

1 “(4) COMPOSITION.—The Committee shall be
2 composed of 7 members, each of whom shall be a
3 voting member. Of the members of the Committee—

4 “(A) not fewer than 2 members shall have
5 broad, general experience in healthcare; and

6 “(B) not fewer than 2 members shall have
7 broad, general experience in the creation of a
8 nonprofit private organization, one of whom
9 shall have expertise in the legal structuring of
10 nonprofit organizations (without regard to
11 whether the individuals have experience in
12 healthcare).

13 “(5) CHAIR.—The Committee shall, from
14 among the members of the Committee, designate an
15 individual to serve as the chair of the Committee.

16 “(6) TERMS; VACANCIES.—The term of mem-
17 bers of the Committee shall be for the duration of
18 the Committee. A vacancy in the membership of the
19 Committee shall not affect the power of the Commit-
20 tee to carry out the duties of the Committee. If a
21 member of the Committee does not serve the full
22 term, the individual appointed to fill the resulting
23 vacancy shall be appointed for the remainder of the
24 term of the predecessor of the individual.

1 “(7) COMPENSATION.—Members of the Com-
 2 mittee may not receive compensation for service on
 3 the Committee. Members of the Committee may be
 4 reimbursed for travel, subsistence, and other nec-
 5 essary expenses incurred in carrying out the duties
 6 of the Committee.

7 “(8) COMMITTEE SUPPORT.—The Director of
 8 the Agency for Healthcare Quality Research may,
 9 from amounts available to the Director for the gen-
 10 eral administration of such Agency, provide staff
 11 and financial support to assist the Committee with
 12 carrying out the functions described in paragraph
 13 (2). In providing such staff and support, the Direc-
 14 tor may both detail employees and contract for as-
 15 sistance.

16 **“PART D—GENERAL PROVISIONS**

17 **“SEC. 931. ADVISORY COUNCIL FOR HEALTHCARE QUALITY**
 18 **RESEARCH.**

19 “(a) ESTABLISHMENT.—There is established an advi-
 20 sory council to be known as the Advisory Council for
 21 Healthcare Quality Research.

22 “(b) DUTIES.—

23 “(1) IN GENERAL.—The Advisory Council shall
 24 advise the Secretary and the Director with respect

1 to activities to carry out the purpose of the Agency
2 under section 901(b).

3 “(2) CERTAIN RECOMMENDATIONS.—Activities
4 of the Advisory Council under paragraph (1) shall
5 include making recommendations to the Director re-
6 garding—

7 “(A) priorities regarding healthcare re-
8 search, especially studies related to quality, out-
9 comes, cost and the utilization of, and access
10 to, healthcare services;

11 “(B) the field of healthcare research and
12 related disciplines, especially issues related to
13 training needs, and dissemination of informa-
14 tion on quality; and

15 “(C) the appropriate role of the Agency in
16 each of these areas in light of private sector ac-
17 tivity and identification of opportunities for
18 public-private sector partnerships.

19 “(c) MEMBERSHIP.—

20 “(1) IN GENERAL.—The Advisory Council shall,
21 in accordance with this subsection, be composed of
22 appointed members and ex officio members. All
23 members of the Advisory Council shall be voting
24 members other than the individuals designated

1 under paragraph (3)(B) who shall be ex officio mem-
2 bers of the Advisory Council.

3 “(2) APPOINTED MEMBERS.—The Secretary
4 shall appoint to the Advisory Council 21 appro-
5 priately qualified individuals. At least 17 members of
6 the Advisory Council shall be representatives of the
7 public who are not officers or employees of the
8 United States. The Secretary shall ensure that the
9 appointed members of the Council, as a group, are
10 representative of professions and entities concerned
11 with, or affected by, activities under this title and
12 under section 1142 of the Social Security Act. Of
13 such members—

14 “(A) 4 shall be individuals distinguished in
15 the conduct of research, demonstration projects,
16 and evaluations with respect to healthcare;

17 “(B) 4 shall be individuals distinguished in
18 the practice of medicine of which at least 1
19 shall be a primary care practitioner;

20 “(C) 3 shall be individuals distinguished in
21 the health professions;

22 “(D) 4 shall be individuals either rep-
23 resenting the private healthcare sector, includ-
24 ing health plans, providers, and purchasers or

1 individuals distinguished as administrators of
2 healthcare delivery systems;

3 “(E) 4 shall be individuals distinguished in
4 the fields of healthcare quality improvement, ec-
5 nomics, information systems, law, ethics, busi-
6 ness, or public policy; and

7 “(F) 2 shall be individuals representing the
8 interests of patients and consumers of
9 healthcare.

10 “(3) EX OFFICIO MEMBERS.—The Secretary
11 shall designate as ex officio members of the Advisory
12 Council—

13 “(A) the Director of the National Insti-
14 tutes of Health, the Director of the Centers for
15 Disease Control and Prevention, the Adminis-
16 trator of the Health Care Financing Adminis-
17 tration, the Assistant Secretary of Defense
18 (Health Affairs), and the Chief Medical Officer
19 of the Department of Veterans Affairs; and

20 “(B) such other Federal officials as the
21 Secretary may consider appropriate.

22 “(d) TERMS.—Members of the Advisory Council ap-
23 pointed under subsection (c)(2) shall serve for a term of
24 3 years. A member of the Council appointed under such

1 subsection may continue to serve after the expiration of
 2 the term of the members until a successor is appointed.

3 “(e) VACANCIES.—If a member of the Advisory
 4 Council appointed under subsection (c)(2) does not serve
 5 the full term applicable under subsection (d), the individ-
 6 ual appointed to fill the resulting vacancy shall be ap-
 7 pointed for the remainder of the term of the predecessor
 8 of the individual.

9 “(f) CHAIR.—The Director shall, from among the
 10 members of the Advisory Council appointed under sub-
 11 section (c)(2), designate an individual to serve as the chair
 12 of the Advisory Council.

13 “(g) MEETINGS.—The Advisory Council shall meet
 14 not less than once during each discrete 4-month period
 15 and shall otherwise meet at the call of the Director or the
 16 chair.

17 “(h) COMPENSATION AND REIMBURSEMENT OF EX-
 18 PENSES.—

19 “(1) APPOINTED MEMBERS.—Members of the
 20 Advisory Council appointed under subsection (c)(2)
 21 shall receive compensation for each day (including
 22 travel time) engaged in carrying out the duties of
 23 the Advisory Council unless declined by the member.
 24 Such compensation may not be in an amount in ex-

1 cess of the maximum rate of basic pay payable for
2 GS-18 of the General Schedule.

3 “(2) EX OFFICIO MEMBERS.—Officials des-
4 ignated under subsection (c)(3) as ex officio mem-
5 bers of the Advisory Council may not receive com-
6 pensation for service on the Advisory Council in ad-
7 dition to the compensation otherwise received for du-
8 ties carried out as officers of the United States.

9 “(i) STAFF.—The Director shall provide to the Advi-
10 sory Council such staff, information, and other assistance
11 as may be necessary to carry out the duties of the Council.

12 **“SEC. 932. PEER REVIEW WITH RESPECT TO GRANTS AND**
13 **CONTRACTS.**

14 “(a) REQUIREMENT OF REVIEW.—

15 “(1) IN GENERAL.—Appropriate technical and
16 scientific peer review shall be conducted with respect
17 to each application for a grant, cooperative agree-
18 ment, or contract under this title.

19 “(2) REPORTS TO DIRECTOR.—Each peer re-
20 view group to which an application is submitted pur-
21 suant to paragraph (1) shall report its finding and
22 recommendations respecting the application to the
23 Director in such form and in such manner as the
24 Director shall require.

1 “(b) APPROVAL AS PRECONDITION OF AWARDS.—

2 The Director may not approve an application described in
3 subsection (a)(1) unless the application is recommended
4 for approval by a peer review group established under sub-
5 section (c).

6 “(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

7 “(1) IN GENERAL.—The Director shall establish
8 such technical and scientific peer review groups as
9 may be necessary to carry out this section. Such
10 groups shall be established without regard to the
11 provisions of title 5, United States Code, that govern
12 appointments in the competitive service, and without
13 regard to the provisions of chapter 51, and sub-
14 chapter III of chapter 53, of such title that relate
15 to classification and pay rates under the General
16 Schedule.

17 “(2) MEMBERSHIP.—The members of any peer
18 review group established under this section shall be
19 appointed from among individuals who by virtue of
20 their training or experience are eminently qualified
21 to carry out the duties of such peer review group.
22 Officers and employees of the United States may not
23 constitute more than 25 percent of the membership
24 of any such group. Such officers and employees may
25 not receive compensation for service on such groups

1 in addition to the compensation otherwise received
2 for duties carried out as such officers and employ-
3 ees.

4 “(3) DURATION.—Notwithstanding section
5 14(a) of the Federal Advisory Committee Act, peer
6 review groups established under this section shall
7 continue in existence until otherwise provided by
8 law.

9 “(4) QUALIFICATIONS.—Members of any peer-
10 review group shall, at a minimum, meet the follow-
11 ing requirements:

12 “(A) Such members shall agree in writing
13 to treat information received, records, reports,
14 and recommendations as confidential informa-
15 tion.

16 “(B) Such members shall agree in writing
17 to recuse themselves from participation in the
18 peer-review of specific applications which
19 present a potential personal conflict of interest
20 or appearance of such conflict, including em-
21 ployment in the applicant organization, stock
22 ownership, or any financial or other arrange-
23 ment that might introduce bias in the process
24 of peer-review.

1 “(d) AUTHORITY FOR PROCEDURAL ADJUSTMENTS
 2 IN CERTAIN CASES.—In the case of applications described
 3 in subsection (a)(1) for financial assistance whose direct
 4 costs will not exceed \$100,000, the Director may make
 5 appropriate adjustments in the procedures otherwise es-
 6 tablished by the Director for the conduct of peer review
 7 under this section. Such adjustments may be made for the
 8 purpose of encouraging the entry of individuals into the
 9 field of research, for the purpose of encouraging clinical
 10 practice-oriented research, and for such other purposes as
 11 the Director may determine to be appropriate.

12 “(e) REGULATIONS.—The Secretary shall issue regu-
 13 lations for the conduct of peer review under this section.

14 **“SEC. 933. CERTAIN PROVISIONS WITH RESPECT TO DEVEL-**
 15 **OPMENT, COLLECTION, AND DISSEMINATION**
 16 **OF DATA.**

17 “(a) STANDARDS WITH RESPECT TO UTILITY OF
 18 DATA.—

19 “(1) IN GENERAL.—With respect to data devel-
 20 oped or collected by any entity for the purpose de-
 21 scribed in section 901(b), the Director shall, in order
 22 to assure that utility, accuracy, and sufficiency of
 23 such data for all interested entities, establish rec-
 24 ommendations for methods of developing and collect-
 25 ing such data. Such recommendations shall include

1 recommendations for the development and collection
2 of data on the outcomes of healthcare services and
3 procedures. Such recommendations shall recognize
4 the differences between types of healthcare plans,
5 delivery systems, healthcare providers, and provider
6 arrangements.

7 “(2) RELATIONSHIP WITH MEDICARE PRO-
8 GRAM.—In any case where recommendations under
9 paragraph (1) may affect the administration of the
10 program under title XVIII of the Social Security
11 Act, they shall be in the form of recommendations
12 to the Secretary for such program.

13 “(b) STATISTICS.—The Director shall—

14 “(1) take such action as may be necessary to
15 assure that statistics developed under this title are
16 of high quality, timely, and comprehensive, as well
17 as specific, standardized, and adequately analyzed
18 and indexed; and

19 “(2) publish, make available, and disseminate
20 such statistics on as wide a basis as is practicable.

21 “(c) AUTHORITY REGARDING CERTAIN REQUESTS.—

22 Upon request of a public or private entity, the Director
23 may undertake research or analyses otherwise authorized
24 by this title pursuant to arrangements under which such
25 entity will pay the cost of the services provided. Amounts

1 received by the Director under such arrangements shall
2 be available to the Director for obligation until expended.

3 **“SEC. 934. DISSEMINATION OF INFORMATION.**

4 “(a) IN GENERAL.—The Administrator shall—

5 “(1) without regard to section 501 of title 44,
6 United States Code, promptly publish, make avail-
7 able, and otherwise disseminate, in a form under-
8 standable and on as broad a basis as practicable so
9 as to maximize its use, the results of research, dem-
10 onstration projects, and evaluations conducted or
11 supported under this title;

12 “(2) promptly make available to the public data
13 developed in such research, demonstration projects,
14 and evaluations;

15 “(3) building upon, but without duplicating, in-
16 formation services provided by the National Library
17 of Medicine and considering applicable interagency
18 agreements, provide indexing, abstracting, translat-
19 ing, publishing, and other services leading to a more
20 effective and timely dissemination of information on
21 research, demonstration projects, and evaluations
22 with respect to healthcare to public and private enti-
23 ties and individuals engaged in the improvement of
24 healthcare delivery and the general public, and un-

1 dertake programs to develop new or improved meth-
2 ods for making such information available; and

3 “(4) as appropriate, provide technical assistance
4 to State and local government and health agencies
5 and conduct liaison activities to such agencies to fos-
6 ter dissemination.

7 “(b) PROHIBITION AGAINST RESTRICTIONS.—Except
8 as provided in subsection (c), the Director may not restrict
9 the publication or dissemination of data from, or the re-
10 sults of, projects conducted or supported under this title.

11 “(c) LIMITATION ON USE OF CERTAIN INFORMA-
12 TION.—No information, if an establishment or person sup-
13 plying the information or described in it is identifiable,
14 obtained in the course of activities undertaken or sup-
15 ported under this title may be used for any purpose other
16 than the purpose for which it was supplied unless such
17 establishment or person has consented (as determined
18 under regulations of the Director) to its use for such other
19 purpose. Such information may not be published or re-
20 leased in other form if the person who supplied the infor-
21 mation or who is described in it is identifiable unless such
22 person has consented (as determined regulations of the
23 Director) to its publication or release in other form.

24 “(d) PENALTY.—Any person who violates subsection
25 (c) shall be subject to a civil monetary penalty of not more

1 than \$10,000 for each such violation involved. Such pen-
 2 alty shall be imposed and collected in the same manner
 3 as civil money penalties under subsection (a) of section
 4 1128A of the Social Security Act are imposed and col-
 5 lected under that section.

6 **“SEC. 935. ADDITIONAL PROVISIONS WITH RESPECT TO**
 7 **GRANTS AND CONTRACTS.**

8 “(a) PRIORITIES.—In establishing priorities to carry
 9 out this title, subject to the availability of funds, the Di-
 10 rector shall consider—

11 “(1) the needs and priorities of healthcare pro-
 12 grams that are operated by or supported, in whole
 13 or in part, by Federal agencies;

14 “(2) the healthcare needs of low-income groups,
 15 minority groups, children, the elderly, and persons
 16 with special healthcare needs and issues related to
 17 the delivery of healthcare services in rural areas (in-
 18 cluding frontier areas).

19 “(b) FINANCIAL CONFLICTS OF INTEREST.—With
 20 respect to projects for which awards of grants, cooperative
 21 agreements, or contracts are authorized to be made under
 22 this title, the Director shall by regulation define—

23 “(1) the specific circumstances that constitute
 24 financial interests in such projects that will, or may
 25 be reasonably expected to, create a bias in favor of

1 obtaining results in the projects that are consistent
2 with such interests; and

3 “(2) the actions that will be taken by the Direc-
4 tor in response to any such interests identified by
5 the Director.

6 “(c) REQUIREMENT OF APPLICATION.—The Director
7 may not, with respect to any program under this title au-
8 thorizing the provision of grants, cooperative agreements,
9 or contracts, provide any such financial assistance unless
10 an application for the assistance is submitted to the Sec-
11 retary and the application is in such form, is made in such
12 manner, and contains such agreements, assurances, and
13 information as the Director determines to be necessary to
14 carry out the program in involved.

15 “(d) PROVISION OF SUPPLIES AND SERVICES IN
16 LIEU OF FUNDS.—

17 “(1) IN GENERAL.—Upon the request of an en-
18 tity receiving a grant, cooperative agreement, or con-
19 tract under this title, the Secretary may, subject to
20 paragraph (2), provide supplies, equipment, and
21 services for the purpose of aiding the entity in carry-
22 ing out the project involved and, for such purpose,
23 may detail to the entity any officer or employee of
24 the Department of Health and Human Services.

1 “(2) CORRESPONDING REDUCTION IN FUNDS.—

2 With respect to a request described in paragraph
3 (1), the Secretary shall reduce the amount of the fi-
4 nancial assistance involved by an amount equal to
5 the costs of detailing personnel and the fair market
6 value of any supplies, equipment, or services pro-
7 vided by the Director. The Secretary shall, for the
8 payment of expenses incurred in complying with
9 such request, expend the amounts withheld.

10 “(e) APPLICABILITY OF CERTAIN PROVISIONS WITH
11 RESPECT TO CONTRACTS.—Contracts may be entered into
12 under this part without regard to sections 3648 and 3709
13 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

14 **“SEC. 936. CERTAIN ADMINISTRATIVE AUTHORITIES.**

15 “(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND
16 EMPLOYEES.—

17 “(1) DEPUTY DIRECTOR.—The Director may
18 appoint a deputy director for the Agency.

19 “(2) OTHER OFFICERS AND EMPLOYEES.—The
20 Director may appoint and fix the compensation of
21 such officers and employees as may be necessary to
22 carry out this title. Except as otherwise provided by
23 law, such officers and employees shall be appointed
24 in accordance with the civil service laws and their

1 compensation fixed in accordance with title 5,
2 United States Code.

3 “(b) FACILITIES.—The Secretary, in carrying out
4 this title—

5 “(1) may acquire, without regard to the Act of
6 March 3, 1877 (40 U.S.C. 34), by lease or otherwise
7 through the Director of General Services, buildings
8 or portions of buildings in the District of Columbia
9 or communities located adjacent to the District of
10 Columbia for use for a period not to exceed 10
11 years; and

12 “(2) may acquire, construct, improve, repair,
13 operate, and maintain laboratory, research, and
14 other necessary facilities and equipment, and such
15 other real or personal property (including patents)
16 as the Secretary deems necessary.

17 “(c) PROVISION OF FINANCIAL ASSISTANCE.—The
18 Director, in carrying out this title, may make grants to
19 public and nonprofit entities and individuals, and may
20 enter into cooperative agreements or contracts with public
21 and private entities and individuals.

22 “(d) UTILIZATION OF CERTAIN PERSONNEL AND RE-
23 SOURCES.—

24 “(1) DEPARTMENT OF HEALTH AND HUMAN
25 SERVICES.—The Director, in carrying out this title,

1 may utilize personnel and equipment, facilities, and
2 other physical resources of the Department of
3 Health and Human Services, permit appropriate (as
4 determined by the Secretary) entities and individuals
5 to utilize the physical resources of such Department,
6 and provide technical assistance and advice.

7 “(2) OTHER AGENCIES.—The Director, in car-
8 rying out this title, may use, with their consent, the
9 services, equipment, personnel, information, and fa-
10 cilities of other Federal, State, or local public agen-
11 cies, or of any foreign government, with or without
12 reimbursement of such agencies.

13 “(e) CONSULTANTS.—The Secretary, in carrying out
14 this title, may secure, from time to time and for such peri-
15 ods as the Director deems advisable but in accordance
16 with section 3109 of title 5, United States Code, the as-
17 sistance and advice of consultants from the United States
18 or abroad.

19 “(f) EXPERTS.—

20 “(1) IN GENERAL.—The Secretary may, in car-
21 rying out this title, obtain the services of not more
22 than 50 experts or consultants who have appropriate
23 scientific or professional qualifications. Such experts
24 or consultants shall be obtained in accordance with
25 section 3109 of title 5, United States Code, except

1 that the limitation in such section on the duration
2 of service shall not apply.

3 “(2) TRAVEL EXPENSES.—

4 “(A) IN GENERAL.—Experts and consult-
5 ants whose services are obtained under para-
6 graph (1) shall be paid or reimbursed for their
7 expenses associated with traveling to and from
8 their assignment location in accordance with
9 sections 5724, 5724a(a), 5724a(c), and
10 5726(C) of title 5, United States Code.

11 “(B) LIMITATION.—Expenses specified in
12 subparagraph (A) may not be allowed in con-
13 nection with the assignment of an expert or
14 consultant whose services are obtained under
15 paragraph (1) unless and until the expert
16 agrees in writing to complete the entire period
17 of assignment, or 1 year, whichever is shorter,
18 unless separated or reassigned for reasons that
19 are beyond the control of the expert or consult-
20 ant and that are acceptable to the Secretary. If
21 the expert or consultant violates the agreement,
22 the money spent by the United States for the
23 expenses specified in subparagraph (A) is recov-
24 erable from the expert or consultant as a debt
25 of the United States. The Secretary may waive

1 in whole or in part a right of recovery under
2 this subparagraph.

3 “(g) VOLUNTARY AND UNCOMPENSATED SERV-
4 ICES.—The Director, in carrying out this title, may accept
5 voluntary and uncompensated services.

6 **“SEC. 937. FUNDING.**

7 “(a) INTENT.—To ensure that the United States’s in-
8 vestment in biomedical research is rapidly translated into
9 improvements in the quality of patient care, there must
10 be a corresponding investment in research on the most ef-
11 fective clinical and organizational strategies for use of
12 these findings in daily practice. The authorization levels
13 in subsections (b) and (c) provide for a proportionate in-
14 crease in healthcare research as the United State’s invest-
15 ment in biomedical research increases.

16 “(b) AUTHORIZATION OF APPROPRIATIONS.—For the
17 purpose of carrying out this title, there are authorized to
18 be appropriated \$180,000,000 for fiscal year 1999, and
19 such sums as may be necessary for each of the fiscal years
20 2000 through 2003.

21 “(c) EVALUATIONS.—In addition to amounts avail-
22 able pursuant to subsection (b) for carrying out this title,
23 there shall be made available for such purpose, from the
24 amounts made available pursuant to section 241 (relating
25 to evaluations), an amount equal to 40 percent of the max-

1 imum amount authorized in such section 241 to be made
2 available for a fiscal year.

3 “(d) CENTERS FOR EDUCATION AND RESEARCH ON
4 THERAPEUTICS.—For the purpose of carrying out the
5 demonstration program regarding centers for education
6 and research on therapeutics under section 912(b), there
7 are authorized to be appropriated \$2,000,000 for fiscal
8 year 1998, and \$3,000,000 for fiscal year 1999, and such
9 sums as may be necessary for each of the fiscal years 2000
10 through 2003.

11 **“SEC. 938. DEFINITIONS.**

12 “In this title:

13 “(1) ADVISORY COUNCIL.—The term ‘Advisory
14 Council’ means the Advisory Council on Healthcare
15 Quality Research established under section 931.

16 “(2) AGENCY.—The term ‘Agency’ means the
17 Agency for Healthcare Quality.

18 “(3) DIRECTOR.—The term ‘Director’ means
19 the Director for the Agency for Healthcare Quality
20 Research.”.

21 **SEC. 403. REFERENCES.**

22 Effective upon the date of enactment of this Act, any
23 reference in law to the “Agency for Health Care Policy
24 and Research” shall be deemed to be a reference to the
25 “Agency for Healthcare Quality Research”.

1 **SEC. 404. STUDY.**

2 (a) STUDY.—Not later than 30 days after the date
 3 of enactment of any Act providing for a qualifying health
 4 care benefit (as defined in subsection (b), the Secretary
 5 of Health and Human Services, in consultation with the
 6 Agency for Healthcare Quality Research, the National In-
 7 stitutes of Health, and the Institute of Medicine, shall con-
 8 duct a study concerning such benefit that scientifically
 9 evaluates—

10 (1) the safety and efficacy of the benefit, par-
 11 ticularly the effect of the benefit on outcomes of
 12 care;

13 (2) the cost, benefits and value of such benefit;

14 (3) the benefit in comparison to alternative ap-
 15 proaches in improving care; and

16 (4) the overall impact that such benefit will
 17 have on health care as measured through research.

18 (b) QUALIFYING HEALTH CARE BENEFIT.—In this
 19 section, the term “qualifying health care benefit” means
 20 a health care benefit that—

21 (1) is disease- or health condition-specific;

22 (2) requires the provision of or coverage for
 23 health care items or services;

24 (3) applies to group health plan, individual
 25 health plans, or health insurance issuers under part
 26 7 of subtitle B of title I of the Employee Retirement

1 Income Security Act of 1974 (29 U.S.C. 1181 et
2 seq.) or under title XXVII of the Public Health
3 Service Act (42 U.S.C. 300gg et seq.); and

4 (4) was provided under an Act (or amendment)
5 enacted on or after January 1, 1998.

6 (c) REPORTS.—Not later than 3 years after the date
7 of enactment of any Act described in subsection (a), the
8 Secretary of Health and Human Services shall prepare
9 and submit to the appropriate committees of Congress a
10 report based on the study conducted under such sub-
11 section with respect to the qualifying health care benefit
12 involved.

13 **TITLE V—WOMEN’S HEALTH** 14 **RESEARCH AND PREVENTION**

15 **SEC. 501. SHORT TITLE.**

16 This title may be cited as the “Women’s Health Re-
17 search and Prevention Amendments of 1998”.

1 **Subtitle A—Provisions Relating to**
2 **Women’s Health Research at the**
3 **National Institutes of Health**

4 **SEC. 511. EXTENSION OF PROGRAM FOR RESEARCH AND**
5 **AUTHORIZATION OF NATIONAL PROGRAM OF**
6 **EDUCATION REGARDING THE DRUG DES.**

7 (a) IN GENERAL.—Section 403A(e) of the Public
8 Health Service Act (42 U.S.C. 283a(e)) is amended by
9 striking “1996” and inserting “2001”.

10 (b) NATIONAL PROGRAM FOR EDUCATION OF
11 HEALTH PROFESSIONALS AND PUBLIC.—From amounts
12 appropriated for carrying out section 403A of the Public
13 Health Service Act (42 U.S.C. 283a), the Secretary of
14 Health and Human Services, acting through the heads of
15 the appropriate agencies of the Public Health Service,
16 shall carry out a national program for the education of
17 health professionals and the public with respect to the
18 drug diethylstilbestrol (commonly known as DES). To the
19 extent appropriate, such national program shall use meth-
20 odologies developed through the education demonstration
21 program carried out under such section 403A. In develop-
22 ing and carrying out the national program, the Secretary
23 shall consult closely with representatives of nonprofit pri-
24 vate entities that represent individuals who have been ex-
25 posed to DES and that have expertise in community-based

1 information campaigns for the public and for health care
 2 providers. The implementation of the national program
 3 shall begin during fiscal year 1999.

4 **SEC. 512. RESEARCH ON OSTEOPOROSIS, PAGET’S DISEASE,**
 5 **AND RELATED BONE DISORDERS.**

6 Section 409A(d) of the Public Health Service Act (42
 7 U.S.C. 284e(d)) is amended by striking “and 1996” and
 8 inserting “through 2001”.

9 **SEC. 513. RESEARCH ON CANCER.**

10 (a) IN GENERAL.—Section 417B(a) of the Public
 11 Health Service Act (42 U.S.C. 286a–8(a)) is amended by
 12 striking “and 1996” and inserting “through 2001”.

13 (b) RESEARCH ON BREAST CANCER.—Section
 14 417B(b)(1) of the Public Health Service Act (42 U.S.C.
 15 286a–8(b)(1)) is amended—

16 (1) in subparagraph (A), by striking “and
 17 1996” and inserting “through 2001”; and

18 (2) in subparagraph (B), by striking “and
 19 1996” and inserting “through 2001”.

20 (c) RESEARCH ON OVARIAN AND RELATED CANCER
 21 RESEARCH.—Section 417B(b)(2) of the Public Health
 22 Service Act (42 U.S.C. 286a–8(b)(2)) is amended by strik-
 23 ing “and 1996” and inserting “through 2001”.

1 **SEC. 514. RESEARCH ON HEART ATTACK, STROKE, AND**
2 **OTHER CARDIOVASCULAR DISEASES IN**
3 **WOMEN.**

4 Subpart 2 of part C of title IV of the Public Health
5 Service Act (42 U.S.C. 285b et seq.) is amended by insert-
6 ing after section 424 the following:

7 “HEART ATTACK, STROKE, AND OTHER CARDIOVASCULAR
8 DISEASES IN WOMEN

9 “SEC. 424A. (a) IN GENERAL.—The Director of the
10 Institute shall expand, intensify, and coordinate research
11 and related activities of the Institute with respect to heart
12 attack, stroke, and other cardiovascular diseases in
13 women.

14 “(b) COORDINATION WITH OTHER INSTITUTES.—
15 The Director of the Institute shall coordinate activities
16 under subsection (a) with similar activities conducted by
17 the other national research institutes and agencies of the
18 National Institutes of Health to the extent that such Insti-
19 tutes and agencies have responsibilities that are related
20 to heart attack, stroke, and other cardiovascular diseases
21 in women.

22 “(c) CERTAIN PROGRAMS.—In carrying out sub-
23 section (a), the Director of the Institute shall conduct or
24 support research to expand the understanding of the
25 causes of, and to develop methods for preventing, cardio-
26 vascular diseases in women. Activities under such sub-

1 section shall include conducting and supporting the follow-
2 ing:

3 “(1) Research to determine the reasons under-
4 lying the prevalence of heart attack, stroke, and
5 other cardiovascular diseases in women, including
6 African-American women and other women who are
7 members of racial or ethnic minority groups.

8 “(2) Basic research concerning the etiology and
9 causes of cardiovascular diseases in women.

10 “(3) Epidemiological studies to address the fre-
11 quency and natural history of such diseases and the
12 differences among men and women, and among ra-
13 cial and ethnic groups, with respect to such diseases.

14 “(4) The development of safe, efficient, and
15 cost-effective diagnostic approaches to evaluating
16 women with suspected ischemic heart disease.

17 “(5) Clinical research for the development and
18 evaluation of new treatments for women, including
19 rehabilitation.

20 “(6) Studies to gain a better understanding of
21 methods of preventing cardiovascular diseases in
22 women, including applications of effective methods
23 for the control of blood pressure, lipids, and obesity.

24 “(7) Information and education programs for
25 patients and health care providers on risk factors as-

1 sociated with heart attack, stroke, and other cardio-
 2 vascular diseases in women, and on the importance
 3 of the prevention or control of such risk factors and
 4 timely referral with appropriate diagnosis and treat-
 5 ment. Such programs shall include information and
 6 education on health-related behaviors that can im-
 7 prove such important risk factors as smoking, obe-
 8 sity, high blood cholesterol, and lack of exercise.

9 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
 10 purpose of carrying out this section, there is authorized
 11 to be appropriated such sums as may be necessary for
 12 each of the fiscal years 1999 through 2001. The author-
 13 ization of appropriations established in the preceding sen-
 14 tence is in addition to any other authorization of appro-
 15 priation that is available for such purpose.”.

16 **SEC. 515. AGING PROCESSES REGARDING WOMEN.**

17 Section 445I of the Public Health Service Act (42
 18 U.S.C. 285e–11) is amended by striking “and 1996” and
 19 inserting “through 2001”.

20 **SEC. 516. OFFICE OF RESEARCH ON WOMEN’S HEALTH.**

21 Section 486(d)(2) of the Public Health Service Act
 22 (42 U.S.C. 287d(d)(2)) is amended by striking “Director
 23 of the Office” and inserting “Director of the National In-
 24 stitutes of Health”.

1 **Subtitle B—Provisions Relating to**
 2 **Women’s Health at the Centers**
 3 **for Disease Control and Preven-**
 4 **tion**

5 **SEC. 521. NATIONAL CENTER FOR HEALTH STATISTICS.**

6 Section 306(n) of the Public Health Service Act (42
 7 U.S.C. 242k(n)) is amended—

8 (1) in paragraph (1), by striking “through
 9 1998” and inserting “through 2002”; and

10 (2) in paragraph (2), by striking “through
 11 1998” and inserting “through 2002”.

12 **SEC. 522. NATIONAL PROGRAM OF CANCER REGISTRIES.**

13 Section 399L(a) of the Public Health Service Act (42
 14 U.S.C. 280e–4(a)) is amended by striking “through 1998”
 15 and inserting “through 2002”.

16 **SEC. 523. NATIONAL BREAST AND CERVICAL CANCER**
 17 **EARLY DETECTION PROGRAM.**

18 (a) GRANTS.—Section 1501(b) of the Public Health
 19 Service Act (42 U.S.C. 300k(b)) is amended—

20 (1) in paragraph (1), by striking “nonprofit”;
 21 and

22 (2) in paragraph (2), by striking “that are not
 23 nonprofit entities”.

24 (b) PREVENTIVE HEALTH.—Section 1509(d) of the
 25 Public Health Service Act (42 U.S.C. 300n–4a(d)(1)) is

1 amended by striking “through 1998” and inserting
 2 “through 2002”.

3 (c) GENERAL PROGRAM.—Section 1510(a) of the
 4 Public Health Service Act (42 U.S.C. 300n–5(a)) is
 5 amended by striking “through 1998” and inserting
 6 “through 2002”.

7 **SEC. 524. CENTERS FOR RESEARCH AND DEMONSTRATION**
 8 **OF HEALTH PROMOTION.**

9 Section 1706(e) of the Public Health Service Act (42
 10 U.S.C. 300u–5(e)) is amended by striking “through
 11 1998” and inserting “through 2002”.

12 **SEC. 525. COMMUNITY PROGRAMS ON DOMESTIC VIO-**
 13 **LENCE.**

14 Section 318(h)(2) of the Family Violence Prevention
 15 and Services Act (42 U.S.C. 10418(h)(2)) is amended by
 16 striking “fiscal year 1997” and inserting “for each of the
 17 fiscal years 1997 through 2002”.

18 **Subtitle C—Women’s Health and**
 19 **Cancer Rights**

20 **SEC. 531. SHORT TITLE.**

21 This subtitle may be cited as the “Women’s Health
 22 and Cancer Rights Act of 1998”.

23 **SEC. 532. FINDINGS.**

24 Congress finds that—

1 (1) the offering and operation of health plans
2 affect commerce among the States;

3 (2) health care providers located in a State
4 serve patients who reside in the State and patients
5 who reside in other States; and

6 (3) in order to provide for uniform treatment of
7 health care providers and patients among the States,
8 it is necessary to cover health plans operating in 1
9 State as well as health plans operating among the
10 several States.

11 **SEC. 533. AMENDMENTS TO THE EMPLOYEE RETIREMENT**
12 **INCOME SECURITY ACT OF 1974.**

13 (a) IN GENERAL.—Subpart B of part 7 of subtitle
14 B of title I of the Employee Retirement Income Security
15 Act of 1974 (29 U.S.C. 1185 et seq.), as amended by sec-
16 tions 111 and 302, is further amended by adding at the
17 end the following new section:

18 **“SEC. 715. REQUIRED COVERAGE FOR MINIMUM HOSPITAL**
19 **STAY FOR MASTECTOMIES AND LYMPH NODE**
20 **DISSECTIONS FOR THE TREATMENT OF**
21 **BREAST CANCER AND COVERAGE FOR RE-**
22 **CONSTRUCTIVE SURGERY FOLLOWING**
23 **MASTECTOMIES.**

24 “(a) INPATIENT CARE.—

1 “(1) IN GENERAL.—A group health plan, and a
2 health insurance issuer providing health insurance
3 coverage in connection with a group health plan,
4 that provides medical and surgical benefits shall en-
5 sure that inpatient coverage with respect to the sur-
6 gical treatment of breast cancer (including a mastec-
7 tomy, lumpectomy, or lymph node dissection for the
8 treatment of breast cancer) is provided for a period
9 of time as is determined by the attending physician,
10 in his or her professional judgment consistent with
11 scientific evidence-based practices or guidelines, in
12 consultation with the patient, to be medically appro-
13 priate.

14 “(2) EXCEPTION.—Nothing in this section shall
15 be construed as requiring the provision of inpatient
16 coverage if the attending physician in consultation
17 with the patient determine that a shorter period of
18 hospital stay is medically appropriate.

19 “(b) RECONSTRUCTIVE SURGERY.—A group health
20 plan, and a health insurance issuer providing health insur-
21 ance coverage in connection with a group health plan, that
22 provides medical and surgical benefits with respect to a
23 mastectomy shall ensure that, in a case in which a mastec-
24 tomy patient elects breast reconstruction, coverage is pro-
25 vided for—

1 “(1) all stages of reconstruction of the breast
2 on which the mastectomy has been performed;

3 “(2) surgery and reconstruction of the other
4 breast to produce a symmetrical appearance; and

5 “(3) the costs of prostheses and complications
6 of mastectomy including lymphedemas;

7 in the manner determined by the attending physician and
8 the patient to be appropriate. Such coverage may be sub-
9 ject to annual deductibles and coinsurance provisions as
10 may be deemed appropriate and as are consistent with
11 those established for other benefits under the plan or cov-
12 erage. Written notice of the availability of such coverage
13 shall be delivered to the participant upon enrollment and
14 annually thereafter.

15 “(c) NOTICE.—A group health plan, and a health in-
16 surance issuer providing health insurance coverage in con-
17 nection with a group health plan shall provide notice to
18 each participant and beneficiary under such plan regard-
19 ing the coverage required by this section in accordance
20 with regulations promulgated by the Secretary. Such no-
21 tice shall be in writing and prominently positioned in any
22 literature or correspondence made available or distributed
23 by the plan or issuer and shall be transmitted—

24 “(1) in the next mailing made by the plan or
25 issuer to the participant or beneficiary;

1 “(2) as part of any yearly informational packet
2 sent to the participant or beneficiary; or
3 “(3) not later than January 1, 1999;
4 whichever is earlier.

5 “(d) NO AUTHORIZATION REQUIRED.—

6 “(1) IN GENERAL.—An attending physician
7 shall not be required to obtain authorization from
8 the plan or issuer for prescribing any length of stay
9 in connection with a mastectomy, a lumpectomy, or
10 a lymph node dissection for the treatment of breast
11 cancer.

12 “(2) PRENOTIFICATION.—Nothing in this sec-
13 tion shall be construed as preventing a group health
14 plan from requiring prenotification of an inpatient
15 stay referred to in this section if such requirement
16 is consistent with terms and conditions applicable to
17 other inpatient benefits under the plan, except that
18 the provision of such inpatient stay benefits shall not
19 be contingent upon such notification.

20 “(e) PROHIBITIONS.—A group health plan, and a
21 health insurance issuer offering group health insurance
22 coverage in connection with a group health plan, may
23 not—

24 “(1) deny to a patient eligibility, or continued
25 eligibility, to enroll or to renew coverage under the

1 terms of the plan, solely for the purpose of avoiding
2 the requirements of this section;

3 “(2) provide monetary payments or rebates to
4 individuals to encourage such individuals to accept
5 less than the minimum protections available under
6 this section;

7 “(3) penalize or otherwise reduce or limit the
8 reimbursement of an attending provider because
9 such provider provided care to an individual partici-
10 pant or beneficiary in accordance with this section;

11 “(4) provide incentives (monetary or otherwise)
12 to an attending provider to induce such provider to
13 provide care to an individual participant or bene-
14 ficiary in a manner inconsistent with this section;
15 and

16 “(5) subject to subsection (f)(2), restrict bene-
17 fits for any portion of a period within a hospital
18 length of stay required under subsection (a) in a
19 manner which is less favorable than the benefits pro-
20 vided for any preceding portion of such stay.

21 “(f) RULES OF CONSTRUCTION.—

22 “(1) IN GENERAL.—Nothing in this section
23 shall be construed to require a patient who is a par-
24 ticipant or beneficiary—

1 “(A) to undergo a mastectomy or lymph
2 node dissection in a hospital; or

3 “(B) to stay in the hospital for a fixed pe-
4 riod of time following a mastectomy or lymph
5 node dissection.

6 “(2) COST SHARING.—Nothing in this section
7 shall be construed as preventing a group health plan
8 or issuer from imposing deductibles, coinsurance, or
9 other cost-sharing in relation to benefits for hospital
10 lengths of stay in connection with a mastectomy or
11 lymph node dissection for the treatment of breast
12 cancer under the plan (or under health insurance
13 coverage offered in connection with a group health
14 plan), except that such coinsurance or other cost-
15 sharing for any portion of a period within a hospital
16 length of stay required under subsection (a) may not
17 be greater than such coinsurance or cost-sharing for
18 any preceding portion of such stay.

19 “(3) LEVEL AND TYPE OF REIMBURSE-
20 MENTS.—Nothing in this section shall be construed
21 to prevent a group health plan or a health insurance
22 issuer offering group health insurance coverage from
23 negotiating the level and type of reimbursement with
24 a provider for care provided in accordance with this
25 section.

1 “(g) PREEMPTION, RELATION TO STATE LAWS.—

2 “(1) IN GENERAL.—Nothing in this section
3 shall be construed to preempt any State law with re-
4 spect to health insurance coverage that—

5 “(A) relates to hospital length of stays
6 after a mastectomy, lumpectomy, or lymph node
7 dissection;

8 “(B) relates to coverage of reconstructive
9 breast surgery after a mastectomy, lumpectomy,
10 of lymph node dissection; or

11 “(C) requires coverage for breast cancer
12 treatments (including breast reconstruction) in
13 accordance with scientific evidence-based prac-
14 tices or guidelines recommended by established
15 medical associations.

16 “(2) APPLICATION OF SECTION.—With respect
17 to a State law—

18 “(A) described in paragraph (1)(A), the
19 provisions of this section relating to breast re-
20 construction shall apply in such State; and

21 “(B) described in paragraph (1)(B), the
22 provisions of this section relating to length of
23 stays for surgical breast treatment shall apply
24 in such State.

“Sec. 715. Required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for reconstructive surgery following mastectomies.”.

12 SEC. 534. AMENDMENTS TO THE PUBLIC HEALTH SERVICE
13 ACT RELATING TO THE GROUP MARKET.

18 **“SEC. 2707. REQUIRED COVERAGE FOR MINIMUM HOSPITAL**
19 **STAY FOR MASTECTOMIES AND LYMPH NODE**
20 **DISSECTIONS FOR THE TREATMENT OF**
21 **BREAST CANCER AND COVERAGE FOR RE-**
22 **CONSTRUCTIVE SURGERY FOLLOWING**
23 **MASTECTOMIES.**

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1 “(1) IN GENERAL.—A group health plan, and a
2 health insurance issuer providing health insurance
3 coverage in connection with a group health plan,
4 that provides medical and surgical benefits shall en-
5 sure that inpatient coverage with respect to the sur-
6 gical treatment of breast cancer (including a mastec-
7 tomy, lumpectomy, or lymph node dissection for the
8 treatment of breast cancer) is provided for a period
9 of time as is determined by the attending physician,
10 in his or her professional judgment consistent with
11 scientific evidence-based practices or guidelines, in
12 consultation with the patient, to be medically appro-
13 priate.

14 “(2) EXCEPTION.—Nothing in this section shall
15 be construed as requiring the provision of inpatient
16 coverage if the attending physician in consultation
17 with the patient determine that a shorter period of
18 hospital stay is medically appropriate.

19 “(b) RECONSTRUCTIVE SURGERY.—A group health
20 plan, and a health insurance issuer providing health insur-
21 ance coverage in connection with a group health plan, that
22 provides medical and surgical benefits with respect to a
23 mastectomy shall ensure that, in a case in which a mastec-
24 tomy patient elects breast reconstruction, coverage is pro-
25 vided for—

1 “(1) all stages of reconstruction of the breast
2 on which the mastectomy has been performed;

3 “(2) surgery and reconstruction of the other
4 breast to produce a symmetrical appearance; and

5 “(3) the costs of prostheses and complications
6 of mastectomy including lymphedemas;

7 in the manner determined by the attending physician and
8 the patient to be appropriate. Such coverage may be sub-
9 ject to annual deductibles and coinsurance provisions as
10 may be deemed appropriate and as are consistent with
11 those established for other benefits under the plan or cov-
12 erage. Written notice of the availability of such coverage
13 shall be delivered to the enrollee upon enrollment and an-
14 nually thereafter.

15 “(c) NOTICE.—A group health plan, and a health in-
16 surance issuer providing health insurance coverage in con-
17 nection with a group health plan shall provide notice to
18 each participant and beneficiary under such plan regard-
19 ing the coverage required by this section in accordance
20 with regulations promulgated by the Secretary. Such no-
21 tice shall be in writing and prominently positioned in any
22 literature or correspondence made available or distributed
23 by the plan or issuer and shall be transmitted—

24 “(1) in the next mailing made by the plan or
25 issuer to the participant or beneficiary;

1 “(2) as part of any yearly informational packet
2 sent to the participant or beneficiary; or
3 “(3) not later than January 1, 1999;
4 whichever is earlier.

5 “(d) NO AUTHORIZATION REQUIRED.—

6 “(1) IN GENERAL.—An attending physician
7 shall not be required to obtain authorization from
8 the plan or issuer for prescribing any length of stay
9 in connection with a mastectomy, a lumpectomy, or
10 a lymph node dissection for the treatment of breast
11 cancer.

12 “(2) PRENOTIFICATION.—Nothing in this sec-
13 tion shall be construed as preventing a plan or
14 issuer from requiring prenotification of an inpatient
15 stay referred to in this section if such requirement
16 is consistent with terms and conditions applicable to
17 other inpatient benefits under the plan, except that
18 the provision of such inpatient stay benefits shall not
19 be contingent upon such notification.

20 “(e) PROHIBITIONS.—A group health plan, and a
21 health insurance issuer offering group health insurance
22 coverage in connection with a group health plan, may
23 not—

24 “(1) deny to a patient eligibility, or continued
25 eligibility, to enroll or to renew coverage under the

1 terms of the plan, solely for the purpose of avoiding
 2 the requirements of this section;

3 “(2) provide monetary payments or rebates to
 4 individuals to encourage such individuals to accept
 5 less than the minimum protections available under
 6 this section;

7 “(3) penalize or otherwise reduce or limit the
 8 reimbursement of an attending provider because
 9 such provider provided care to an individual partici-
 10 pant or beneficiary in accordance with this section;

11 “(4) provide incentives (monetary or otherwise)
 12 to an attending provider to induce such provider to
 13 provide care to an individual participant or bene-
 14 ficiary in a manner inconsistent with this section;
 15 and

16 “(5) subject to subsection (f)(2), restrict bene-
 17 fits for any portion of a period within a hospital
 18 length of stay required under subsection (a) in a
 19 manner which is less favorable than the benefits pro-
 20 vided for any preceding portion of such stay.

21 “(f) RULES OF CONSTRUCTION.—

22 “(1) IN GENERAL.—Nothing in this section
 23 shall be construed to require a patient who is a par-
 24 ticipant or beneficiary—

1 “(A) to undergo a mastectomy or lymph
2 node dissection in a hospital; or

3 “(B) to stay in the hospital for a fixed pe-
4 riod of time following a mastectomy or lymph
5 node dissection.

6 “(2) COST SHARING.—Nothing in this section
7 shall be construed as preventing a group health plan
8 or issuer from imposing deductibles, coinsurance, or
9 other cost-sharing in relation to benefits for hospital
10 lengths of stay in connection with a mastectomy or
11 lymph node dissection for the treatment of breast
12 cancer under the plan (or under health insurance
13 coverage offered in connection with a group health
14 plan), except that such coinsurance or other cost-
15 sharing for any portion of a period within a hospital
16 length of stay required under subsection (a) may not
17 be greater than such coinsurance or cost-sharing for
18 any preceding portion of such stay.

19 “(3) LEVEL AND TYPE OF REIMBURSE-
20 MENTS.—Nothing in this section shall be construed
21 to prevent a group health plan or a health insurance
22 issuer offering group health insurance coverage from
23 negotiating the level and type of reimbursement with
24 a provider for care provided in accordance with this
25 section.

1 “(g) PREEMPTION, RELATION TO STATE LAWS.—

2 “(1) IN GENERAL.—Nothing in this section
3 shall be construed to preempt any State law with re-
4 spect to health insurance coverage that—

5 “(A) relates to a hospital length of stay
6 after a mastectomy, lumpectomy, or lymph node
7 dissection;

8 “(B) relates to coverage of reconstructive
9 breast surgery after a mastectomy, lumpectomy,
10 or lymph node dissection; or

11 “(C) requires coverage for breast cancer
12 treatments (including breast reconstruction) in
13 accordance with scientific evidence-based prac-
14 tices or guidelines recommended by established
15 medical associations.

16 “(2) APPLICATION OF SECTION.—With respect
17 to a State law—

18 “(A) described in paragraph (1)(A), the
19 provisions of this section relating to breast re-
20 construction shall apply in such State; and

21 “(B) described in paragraph (1)(B), the
22 provisions of this section relating to length of
23 stays for surgical breast treatment shall apply
24 in such State.

1 “(3) ERISA.—Nothing in this section shall be
 2 construed to affect or modify the provisions of sec-
 3 tion 514 with respect to group health plans.”.

4 (b) EFFECTIVE DATES.—The amendments made by
 5 this section shall apply to group health plans for plan
 6 years beginning on or after the date of enactment of this
 7 Act.

8 **SEC. 535. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
 9 **ACT RELATING TO THE INDIVIDUAL MARKET.**

10 (a) IN GENERAL.—Subpart 3 of part B of title
 11 XXVII of the Public Health Service Act (42 U.S.C.
 12 300gg–51 et seq.), as amended by section 303(b), is fur-
 13 ther amended by adding at the end the following new sec-
 14 tion:

15 **“SEC. 2753. REQUIRED COVERAGE FOR MINIMUM HOSPITAL**
 16 **STAY FOR MASTECTOMIES AND LYMPH NODE**
 17 **DISSECTIONS FOR THE TREATMENT OF**
 18 **BREAST CANCER.**

19 “The provisions of section 2707 shall apply to health
 20 insurance coverage offered by a health insurance issuer
 21 in the individual market in the same manner as they apply
 22 to health insurance coverage offered by a health insurance
 23 issuer in connection with a group health plan in the small
 24 or large group market.”.

1 (b) EFFECTIVE DATE.—The amendment made by
 2 this section shall apply with respect to health insurance
 3 coverage offered, sold, issued, renewed, in effect, or oper-
 4 ated in the individual market on or after the date of enact-
 5 ment of this Act.

6 **SEC. 536. AMENDMENTS TO THE INTERNAL REVENUE CODE**
 7 **OF 1986.**

8 (a) IN GENERAL.—Subchapter A of chapter 100 of
 9 the Internal Revenue Code of 1986 (relating to group
 10 health plan portability, access, and renewability require-
 11 ments) is amended by inserting after section 9803 the fol-
 12 lowing new section:

13 **“SEC. 9804. REQUIRED COVERAGE FOR MINIMUM HOSPITAL**
 14 **STAY FOR MASTECTOMIES AND LYMPH NODE**
 15 **DISSECTIONS FOR THE TREATMENT OF**
 16 **BREAST CANCER AND COVERAGE FOR RE-**
 17 **CONSTRUCTIVE SURGERY FOLLOWING**
 18 **MASTECTOMIES.**

19 “(a) INPATIENT CARE.—

20 “(1) IN GENERAL.—A group health plan, and a
 21 health insurance issuer providing health insurance
 22 coverage in connection with a group health plan,
 23 that provides medical and surgical benefits shall en-
 24 sure that inpatient coverage with respect to the sur-
 25 gical treatment of breast cancer (including a mastec-

1 tomy, lumpectomy, or lymph node dissection for the
 2 treatment of breast cancer) is provided for a period
 3 of time as is determined by the attending physician,
 4 in his or her professional judgment consistent with
 5 scientific evidence-based practices or guidelines, in
 6 consultation with the patient, to be medically appro-
 7 priate.

8 “(2) EXCEPTION.—Nothing in this section shall
 9 be construed as requiring the provision of inpatient
 10 coverage if the attending physician in consultation
 11 with the patient determine that a shorter period of
 12 hospital stay is medically appropriate.

13 “(b) RECONSTRUCTIVE SURGERY.—A group health
 14 plan, and a health insurance issuer providing health insur-
 15 ance coverage in connection with a group health plan, that
 16 provides medical and surgical benefits with respect to a
 17 mastectomy shall ensure that, in a case in which a mastec-
 18 tomy patient elects breast reconstruction, coverage is pro-
 19 vided for—

20 “(1) all stages of reconstruction of the breast
 21 on which the mastectomy has been performed;

22 “(2) surgery and reconstruction of the other
 23 breast to produce a symmetrical appearance; and

24 “(3) the costs of prostheses and complications
 25 of mastectomy including lymphedemas;

1 in the manner determined by the attending physician and
 2 the patient to be appropriate. Such coverage may be sub-
 3 ject to annual deductibles and coinsurance provisions as
 4 may be deemed appropriate and as are consistent with
 5 those established for other benefits under the plan or cov-
 6 erage. Written notice of the availability of such coverage
 7 shall be delivered to the participant upon enrollment and
 8 annually thereafter.

9 “(c) NOTICE.—A group health plan, and a health in-
 10 surance issuer providing health insurance coverage in con-
 11 nection with a group health plan shall provide notice to
 12 each participant and beneficiary under such plan regard-
 13 ing the coverage required by this section in accordance
 14 with regulations promulgated by the Secretary. Such no-
 15 tice shall be in writing and prominently positioned in any
 16 literature or correspondence made available or distributed
 17 by the plan or issuer and shall be transmitted—

18 “(1) in the next mailing made by the plan or
 19 issuer to the participant or beneficiary;

20 “(2) as part of any yearly informational packet
 21 sent to the participant or beneficiary; or

22 “(3) not later than January 1, 1999;
 23 whichever is earlier.

24 “(d) NO AUTHORIZATION REQUIRED.—

1 “(1) IN GENERAL.—A, attending physician
2 shall not be required to obtain authorization from
3 the plan or issuer for prescribing any length of stay
4 in connection with a mastectomy, a lumpectomy, or
5 a lymph node dissection for the treatment of breast
6 cancer.

7 “(2) PRENOTIFICATION.—Nothing in this sec-
8 tion shall be construed as preventing a plan or
9 issuer from requiring prenotification of an inpatient
10 stay referred to in this section if such requirement
11 is consistent with terms and conditions applicable to
12 other inpatient benefits under the plan, except that
13 the provision of such inpatient stay benefits shall not
14 be contingent upon such notification.

15 “(e) PROHIBITIONS.—A group health plan, and a
16 health insurance issuer offering group health insurance
17 coverage in connection with a group health plan, may
18 not—

19 “(1) deny to a patient eligibility, or continued
20 eligibility, to enroll or to renew coverage under the
21 terms of the plan, solely for the purpose of avoiding
22 the requirements of this section;

23 “(2) provide monetary payments or rebates to
24 individuals to encourage such individuals to accept

1 less than the minimum protections available under
 2 this section;

3 “(3) penalize or otherwise reduce or limit the
 4 reimbursement of an attending provider because
 5 such provider provided care to an individual partici-
 6 pant or beneficiary in accordance with this section;

7 “(4) provide incentives (monetary or otherwise)
 8 to an attending provider to induce such provider to
 9 provide care to an individual participant or bene-
 10 ficiary in a manner inconsistent with this section;
 11 and

12 “(5) subject to subsection (f)(2), restrict bene-
 13 fits for any portion of a period within a hospital
 14 length of stay required under subsection (a) in a
 15 manner which is less favorable than the benefits pro-
 16 vided for any preceding portion of such stay.

17 “(f) RULES OF CONSTRUCTION.—

18 “(1) IN GENERAL.—Nothing in this section
 19 shall be construed to require a patient who is a par-
 20 ticipant or beneficiary—

21 “(A) to undergo a mastectomy or lymph
 22 node dissection in a hospital; or

23 “(B) to stay in the hospital for a fixed pe-
 24 riod of time following a mastectomy or lymph
 25 node dissection.

1 “(2) COST SHARING.—Nothing in this section
2 shall be construed as preventing a group health plan
3 or issuer from imposing deductibles, coinsurance, or
4 other cost-sharing in relation to benefits for hospital
5 lengths of stay in connection with a mastectomy or
6 lymph node dissection for the treatment of breast
7 cancer under the plan (or under health insurance
8 coverage offered in connection with a group health
9 plan), except that such coinsurance or other cost-
10 sharing for any portion of a period within a hospital
11 length of stay required under subsection (a) may not
12 be greater than such coinsurance or cost-sharing for
13 any preceding portion of such stay.

14 “(3) LEVEL AND TYPE OF REIMBURSE-
15 MENTS.—Nothing in this section shall be construed
16 to prevent a group health plan or a health insurance
17 issuer offering group health insurance coverage from
18 negotiating the level and type of reimbursement with
19 a provider for care provided in accordance with this
20 section.

21 “(g) PREEMPTION, RELATION TO STATE LAWS.—

22 “(1) IN GENERAL.—Nothing in this section
23 shall be construed to preempt any State law with re-
24 spect to health insurance coverage that—

1 “(A) relates to a hospital length of stay
2 after a mastectomy, lumpectomy, or lymph node
3 dissection;

4 “(B) relates to coverage of reconstructive
5 breast surgery after a mastectomy, lumpectomy,
6 or lymph node dissection; or

7 “(C) requires coverage for breast cancer
8 treatments (including breast reconstruction) in
9 accordance with scientific evidence-based prac-
10 tices or guidelines recommended by established
11 medical associations.

12 “(2) APPLICATION OF SECTION.—With respect
13 to a State law—

14 “(A) described in paragraph (1)(A), the
15 provisions of this section relating to breast re-
16 construction shall apply in such State; and

17 “(B) described in paragraph (1)(B), the
18 provisions of this section relating to length of
19 stays for surgical breast treatment shall apply
20 in such State.

21 “(3) ERISA.—Nothing in this section shall be
22 construed to affect or modify the provisions of sec-
23 tion 514 with respect to group health plans.”.

24 (b) CONFORMING AMENDMENTS.—

1 (1) The heading for subtitle K of such Code is
 2 amended to read as follows:

3 **“Subtitle K—Group Health Plan**
 4 **Portability, Access, Renewabil-**
 5 **ity, and Other Requirements”.**

6 (2) The heading for chapter 100 of such Code
 7 is amended to read as follows:

8 **“CHAPTER 100—GROUP HEALTH PLAN PORT-**
 9 **ABILITY, ACCESS, RENEWABILITY, AND**
 10 **OTHER REQUIREMENTS”.**

11 (3) Section 4980D(a) of such Code is amended
 12 by striking “and renewability” and inserting “renew-
 13 ability, and other”.

14 (c) CLERICAL AMENDMENTS.—

15 (1) The table of contents for chapter 100 of
 16 such Code is amended inserting after the item relat-
 17 ing to section 9803 the following new item:

“Sec. 9804. Required coverage for minimum hospital stay for mastectomies and
 lymph node dissections for the treatment of breast cancer and
 coverage for reconstructive surgery following mastectomies.”.

18 (2) The item relating to subtitle K in the table
 19 of subtitles for such Code is amended by striking
 20 “and renewability” and inserting “renewability, and
 21 other”.

22 (3) The item relating to chapter 100 in the
 23 table of chapters for subtitle K of such Code is

1 amended by striking “and renewability” and insert-
2 ing “renewability, and other”.

3 (d) EFFECTIVE DATES.—The amendments made by
4 this section shall apply with respect to plan years begin-
5 ning on or after the date of enactment of this Act.

6 **SEC. 537. RESEARCH STUDY ON THE MANAGEMENT OF**
7 **BREAST CANCER.**

8 (a) STUDY.—To improve survival, quality of life and
9 patient satisfaction in the care of patients with breast can-
10 cer, the Agency for Health Care Policy and Research shall
11 conduct a study of the scientific issues relating to—

12 (1) disease management strategies for breast
13 cancer that can achieve better patient outcomes;

14 (2) controlled clinical evidence that links spe-
15 cific clinical procedures to improved health out-
16 comes;

17 (3) the definition of quality measures to evalu-
18 ate plan and provider performance in the manage-
19 ment of breast cancer;

20 (4) the identification of quality improvement
21 interventions that can change the process of care to
22 achieve better outcomes for individuals with breast
23 cancer;

24 (5) preventive strategies utilized by health plans
25 for the treatment of breast cancer; and

1 (6) the extent of clinical practice variation in-
 2 cluding its impact on cost, quality and outcomes.

3 (b) REPORT.—Not later than January 1, 2000, the
 4 Agency for Health Care Policy and Research shall prepare
 5 and submit to the appropriate committees of Congress a
 6 report concerning the results of the study conducted under
 7 subsection (a).

8 **TITLE VI—ENHANCED ACCESS**
 9 **TO HEALTH INSURANCE COV-**
 10 **ERAGE**

11 **SEC. 601. CARRYOVER OF UNUSED BENEFITS FROM CAFETERIA PLANS, FLEXIBLE SPENDING ARRANGEMENTS, AND HEALTH FLEXIBLE SPENDING ACCOUNTS.**

15 (a) IN GENERAL.—Section 125 of the Internal Revenue Code of 1986 (relating to cafeteria plans) is amended
 16 by redesignating subsections (h) and (i) as subsections (i)
 17 and (j) and by inserting after subsection (g) the following
 18 new subsection:
 19

20 “(h) ALLOWANCE OF CARRYOVERS OF UNUSED BENEFITS TO LATER TAXABLE YEARS.—

22 “(1) IN GENERAL.—For purposes of this title—
 23 “(A) a plan or other arrangement shall not
 24 fail to be treated as a cafeteria plan or flexible
 25 spending or similar arrangement, and

1 “(B) no amount shall be required to be in-
2 cluded in gross income by reason of this section
3 or any other provision of this chapter,
4 solely because under such plan or other arrangement
5 any nontaxable benefit which is unused as of the
6 close of a taxable year may be carried forward to 1
7 or more succeeding taxable years.

8 “(2) LIMITATION.—Paragraph (1) shall not
9 apply to amounts carried from a plan to the extent
10 such amounts exceed \$500 (applied on an annual
11 basis). For purposes of this paragraph, all plans and
12 arrangements maintained by an employer or any re-
13 lated person shall be treated as 1 plan.

14 “(3) ALLOWANCE OF ROLLOVER.—

15 “(A) IN GENERAL.—In the case of any un-
16 used benefit described in paragraph (1) which
17 consists of amounts in a health flexible spend-
18 ing account or dependent care flexible spending
19 account, the plan or arrangement shall provide
20 that a participant may elect, in lieu of such car-
21 ryover, to have such amounts distributed to the
22 participant.

23 “(B) AMOUNTS NOT INCLUDED IN IN-
24 COME.—Any distribution under subparagraph
25 (A) shall not be included in gross income to the

1 extent that such amount is transferred in a
 2 trustee-to-trustee transfer, or is contributed
 3 within 60 days of the date of the distribution,
 4 to—

5 “(i) an individual retirement plan
 6 other than a Roth IRA (as defined in sec-
 7 tion 408A(b)),

8 “(ii) a qualified cash or deferred ar-
 9 rangement described in section 401(k),

10 “(iii) a plan under which amounts are
 11 contributed by an individual’s employer for
 12 an annuity contract described in section
 13 403(b),

14 “(iv) an eligible deferred compensa-
 15 tion plan described in section 457, or

16 “(v) a medical savings account (within
 17 the meaning of section 220).

18 Any amount rolled over under this subpara-
 19 graph shall be treated as a rollover contribution
 20 for the taxable year from which the unused
 21 amount would otherwise be carried.

22 “(C) TREATMENT OF ROLLOVER.—Any
 23 amount rolled over under subparagraph (B)
 24 shall be treated as an eligible rollover under
 25 section 219, 220, 401(k), 403(b), or 457,

1 whichever is applicable, and shall not be taken
 2 into account in applying any limitation (or par-
 3 ticipation requirement) on employer or em-
 4 ployee contributions under such section or any
 5 other provision of this chapter for the taxable
 6 year of the rollover.

7 “(4) COST-OF-LIVING ADJUSTMENT.—In the
 8 case of any taxable year beginning in a calendar
 9 year after 1998, the \$500 amount under paragraph
 10 (2) shall be adjusted at the same time and in the
 11 same manner as under section 415(d)(2), except
 12 that the base period taken into account shall be the
 13 calendar quarter beginning October 1, 1997, and
 14 any increase which is not a multiple of \$50 shall be
 15 rounded to the next lowest multiple of \$50.”

16 (b) EFFECTIVE DATE.—The amendments made by
 17 this section shall apply to taxable years beginning after
 18 December 31, 1998.

19 **SEC. 602. FULL DEDUCTION OF HEALTH INSURANCE COSTS**
 20 **FOR SELF-EMPLOYED INDIVIDUALS.**

21 (a) IN GENERAL.—Section 162(l)(1) of the Internal
 22 Revenue Code of 1986 (relating to allowance of deduc-
 23 tions) is amended to read as follows:

24 “(1) ALLOWANCE OF DEDUCTION.—In the case
 25 of an individual who is an employee within the

1 meaning of section 401(c)(1), there shall be allowed
 2 as a deduction under this section an amount equal
 3 to the amount paid during the taxable year for in-
 4 surance which constitutes medical care for the tax-
 5 payer, his spouse, and his dependents.”

6 (b) EFFECTIVE DATE.—The amendments made by
 7 this section shall apply to taxable years beginning after
 8 December 31, 1998.

9 **SEC. 603. FULL AVAILABILITY OF MEDICAL SAVINGS AC-**
 10 **COUNTS.**

11 (a) AVAILABILITY NOT LIMITED TO ACCOUNTS FOR
 12 EMPLOYEES OF SMALL EMPLOYERS AND SELF-EM-
 13 PLOYED INDIVIDUALS.—

14 (1) IN GENERAL.—Section 220(c)(1)(A) of the
 15 Internal Revenue Code of 1986 (relating to eligible
 16 individual) is amended to read as follows:

17 “(A) IN GENERAL.—The term ‘eligible in-
 18 dividual’ means, with respect to any month, any
 19 individual if—

20 “(i) such individual is covered under a
 21 high deductible health plan as of the 1st
 22 day of such month, and

23 “(ii) such individual is not, while cov-
 24 ered under a high deductible health plan,
 25 covered under any health plan—

1 “(I) which is not a high deduct-
2 ible health plan, and

3 “(II) which provides coverage for
4 any benefit which is covered under the
5 high deductible health plan.”.

6 (2) CONFORMING AMENDMENTS.—

7 (A) Section 220(c)(1) of such Code is
8 amended by striking subparagraphs (C) and
9 (D).

10 (B) Section 220(c) of such Code is amend-
11 ed by striking paragraph (4) (defining small
12 employer) and by redesignating paragraph (5)
13 as paragraph (4).

14 (C) Section 220(b) of such Code is amend-
15 ed by striking paragraph (4) (relating to deduc-
16 tion limited by compensation) and by redesign-
17 ating paragraphs (5), (6), and (7) as para-
18 graphs (4), (5), and (6), respectively.

19 (b) REMOVAL OF LIMITATION ON NUMBER OF TAX-
20 PAYERS HAVING MEDICAL SAVINGS ACCOUNTS.—

21 (1) IN GENERAL.—Section 220 of the Internal
22 Revenue Code of 1986 (relating to medical savings
23 accounts) is amended by striking subsections (i) and
24 (j).

1 (2) MEDICARE+CHOICE.—Section 138 of such
2 Code (relating to Medicare+Choice MSA) is amend-
3 ed by striking subsection (f).

4 (c) REDUCTION IN HIGH DEDUCTIBLE PLAN MINI-
5 MUM ANNUAL DEDUCTIBLE.—Section 220(c)(2)(A) of the
6 Internal Revenue Code of 1986 (relating to high deduct-
7 ible health plan) is amended—

8 (1) by striking “\$1,500” in clause (i) and in-
9 serting “\$1,000”, and

10 (2) by striking “\$3,000” in clause (ii) and in-
11 serting “\$2,000”.

12 (d) INCREASE IN CONTRIBUTION LIMIT TO 100 PER-
13 CENT OF ANNUAL DEDUCTIBLE.—

14 (1) IN GENERAL.—Section 220(b)(2) of the In-
15 ternal Revenue Code of 1986 (relating to monthly
16 limitation) is amended to read as follows:

17 “(2) MONTHLY LIMITATION.—The monthly lim-
18 itation for any month is the amount equal to $\frac{1}{12}$ of
19 the annual deductible of the high deductible health
20 plan of the individual.”

21 (2) CONFORMING AMENDMENT.—Section
22 220(d)(1)(A) of such Code is amended by striking
23 “75 percent of”.

24 (e) LIMITATION ON ADDITIONAL TAX ON DISTRIBUTI-
25 ONS NOT USED FOR QUALIFIED MEDICAL EX-

1 PENSES.—Section 220(f)(4) of the Internal Revenue Code
 2 of 1986 (relating to additional tax on distributions not
 3 used for qualified medical expenses) is amended by adding
 4 at the end the following:

5 “(D) EXCEPTION IN CASE OF SUFFICIENT
 6 ACCOUNT BALANCE.—Subparagraph (A) shall
 7 not apply to any payment or distribution in any
 8 taxable year, but only to the extent such pay-
 9 ment or distribution does not reduce the fair
 10 market value of the assets of the medical sav-
 11 ings account to an amount less than the annual
 12 deductible for the high deductible health plan of
 13 the account holder (determined as of January 1
 14 of the calendar year in which the taxable year
 15 begins).”.

16 (f) EFFECTIVE DATE.—The amendments made by
 17 this section shall apply to taxable years beginning after
 18 December 31, 1998.

19 **SEC. 604. PERMITTING CONTRIBUTION TOWARDS MEDICAL**
 20 **SAVINGS ACCOUNT THROUGH FEDERAL EM-**
 21 **PLOYEES HEALTH BENEFITS PROGRAM**
 22 **(FEHBP).**

23 (a) GOVERNMENT CONTRIBUTION TO MEDICAL SAV-
 24 INGS ACCOUNT.—

1 (1) IN GENERAL.—Section 8906 of title 5,
2 United States Code, is amended by adding at the
3 end the following:

4 “(j)(1) In the case of an employee or annuitant who
5 is enrolled in a catastrophic plan described by section
6 8903(5), there shall be a Government contribution under
7 this subsection to a medical savings account established
8 or maintained for the benefit of the individual. The con-
9 tribution under this subsection shall be in addition to the
10 Government contribution under subsection (b).

11 “(2) The amount of the Government contribution
12 under this subsection with respect to an individual is equal
13 to the amount by which—

14 “(A) the maximum contribution allowed under
15 subsection (b)(1) with respect to any employee or
16 annuitant, exceeds

17 “(B) the amount of the Government contribu-
18 tion actually made with respect to the individual
19 under subsection (b) for coverage under the cata-
20 strophic plan.

21 “(3) The Government contributions under this sub-
22 section shall be paid into a medical savings account (des-
23 ignated by the individual involved) in a manner that is
24 specified by the Office and consistent with the timing of
25 contributions under subsection (b).

1 “(4) Subsections (f) and (g) shall apply to contribu-
 2 tions under this section in the same manner as they apply
 3 to contributions under subsection (b).

4 “(5) For the purpose of this subsection, the term
 5 ‘medical savings account’ has the meaning given such term
 6 by section 220(d) of the Internal Revenue Code of 1986.”.

7 (2) ALLOWING PAYMENT OF FULL AMOUNT OF
 8 CHARGE FOR CATASTROPHIC PLAN.—Section
 9 8906(b)(2) of such title is amended by inserting “(or
 10 100 percent of the subscription charge in the case
 11 of a catastrophic plan)” after “75 percent of the
 12 subscription charge”.

13 (b) OFFERING OF CATASTROPHIC PLANS.—

14 (1) IN GENERAL.—Section 8903 of title 5,
 15 United States Code, is amended by adding at the
 16 end the following:

17 “(5) CATASTROPHIC PLANS.—One or more
 18 plans described in paragraph (1), (2), or (3), but
 19 which provide benefits of the types referred to by
 20 paragraph (5) of section 8904(a), instead of the
 21 types referred to in paragraphs (1), (2), and (3) of
 22 such section.”.

23 (2) TYPES OF BENEFITS.—Section 8904(a) of
 24 such title is amended by inserting after paragraph
 25 (4) the following new paragraph:

1 “(5) CATASTROPHIC PLANS.—Benefits of the
2 types named under paragraph (1) or (2) of this sub-
3 section or both, to the extent expenses covered by
4 the plan exceed \$500.”.

5 (3) DISREGARDING CATASTROPHIC PLANS IN
6 DETERMINING LEVEL OF GOVERNMENT CONTRIBU-
7 TIONS.—Section 8906(a)(3) of such title is amended
8 by inserting “described by section 8903(3)” after
9 “plans”.

10 (c) EFFECTIVE DATE.—The amendments made by
11 this section shall apply to contract terms beginning on or
12 after January 1, 1999.